UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION

UNITED STATES OF AMERICA, and THE STATE OF NORTH CAROLINA, *ex rel.* LISA WHEELER Plaintiffs, vs. ACADIA HEALTHCARE COMPANY, INC.; CRC HEALTH, LLC; ATS OF NORTH CAROLINA, LLC d/b/a MOUNTAIN HEALTH SOLUTIONS ASHEVILLE, d/b/a ASHEVILLE COMPREHENSIVE TREATMENT CENTER, d/b/a MOUNTAIN HEALTH SOLUTIONS NORTH WILKESBORO (MHS), d/b/a NORTH WILKESBORO COMPREHENSIVE TREATMENT CENTER. Defendants.	Case No. 1:21-cv-241 **AMENDED COMPLAINT** DEMAND FOR JURY TRIAL

NOW COMES PLAINTIFF-RELATOR, Lisa Wheeler, by and through her attorneys, on behalf of the United States of America ("United States") and the State of North Carolina to recover losses from false claims submitted to Medicare, Medicaid, TRICARE, the Department of Veterans Affairs, the North Carolina Department of Health and Human Services ("NC DHHS"), and other state and federal healthcare programs (collectively, "Government Healthcare Programs") as a result of the sustained fraudulent conduct of Defendants Acadia Healthcare Company, Inc. ("Acadia"), CRC Health, LLC ("CRC"), and ATS of North Carolina, LLC, d/b/a Mountain Health So-

lutions Asheville, d/b/a Asheville Comprehensive Treatment Center, d/b/a Mountain Health Solutions North Wilkesboro (MHS), d/b/a North Wilkesboro Comprehensive Treatment Center ("ATS").

This action is brought under the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"), seeking treble damages and civil penalties, as well as the North Carolina False Claims Act, N.C. Gen. Stat. § 1-607, *et seq*., and other laws as set forth herein.

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I. INTRODUCTION

1. The United States is in the throes of an opioid epidemic that has devastated the lives of many families.

2. While the opioid epidemic long predated the COVID-19 pandemic, the joblessness, depression, and sense of isolation created by the pandemic have exacerbated the opioid epidemic.

3. In response, Government Healthcare Programs have spent billions of dollars to abate this crisis.

4. Unfortunately, many medical and behavioral health providers have seized on the opportunity to submit false and fraudulent claims for substance abuse treatment.

5. In recent years, Defendant CRC has paid more than $25 Million to resolve claims that it engaged in fraudulent billing practices for substance abuse treatment.

6. In April 2014, Defendant CRC agreed to pay $9.25 Million to the United States and the State of Tennessee to settle allegations that it knowingly submitted false claims to the Tennessee Medicaid Program for substance abuse therapy services that were not provided or were provided by therapists lacking the proper licensure.

7. In May 2019, Defendant CRC, which was acquired by Defendant Acadia in October 2014, entered into a $17 Million settlement with the United States and the State of West Virginia for allegedly submitting false and fraudulent drug testing claims for Medicaid patients.

8. Defendant Acadia and Defendant CRC also entered into a five-year Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG").

9. The CIA imposed training, compliance, risk assessment, and disclosure requirements and requires that Defendants report any probable violations of criminal, civil, or administrative healthcare laws to the United States.

10. Despite being subject to the requirements of the CIA, Defendants have engaged in systematic and widespread fraud by falsifying group therapy treatment notes and providing inadequate counseling and therapy for patients in drug treatment.

11. Defendants own and operate behavioral healthcare facilities that treat Opioid Use Disorder.

12. Upon information and belief, Defendants have received hundreds of millions of dollars—if not more—from Government Healthcare Programs for this treatment.

13. One of the primary services offered by Defendants is Medication-Assisted Treatment ("MAT") for individuals diagnosed with an Opioid Use Disorder.

14. MAT involves the use of medications, in combination with counseling and therapy, to treat addiction, including Opioid Use Disorder.

15. Defendants treat Opioid Use Disorder with MAT in a variety of settings, including inpatient, intensive outpatient, Opioid Treatment Programs ("OTPs"), and Office Based Opioid Treatment ("OBOT").

16. While Defendants can prescribe some medications for Opioid Use Disorder in an outpatient setting, OTPs are the only setting in which Methadone can be legally prescribed and dispensed.

17. Generally, patients visit an OTP daily to receive their dose of Methadone or Buprenorphine.

18. Many beneficiaries of Government Healthcare Programs have sought treatment from Defendants, including OTP services.

19. OTPs must be certified by the Substance Abuse and Mental Health Services Administration ("SAMHSA") and be accredited by an accrediting body approved by SAMHSA.

20. OTPs are also required to comply with state and federal opioid treatment regulations and standards.

21. For example, OTPs must:

a. "[P]rovide adequate medical, counseling, vocational, educational, and other assessment and treatment services" and "be able to document that these services are fully and reasonably available to patients." 42 C.F.R. § 8.12(f)(1).

b. Assess each patient upon admission and periodically "to determine the most appropriate combination of services and treatment." *Id.* § 8.12(f)(4).

c. Prepare a treatment plan that contains "the medical, psychosocial, economic, legal, or other supportive services that a patient needs" and identifies "the frequency with which these services are to be provided." *Id.* This treatment plan must be reviewed and updated throughout treatment to reflect the patient's "current needs." *Id.*

d. "[P]rovide adequate substance abuse counseling to each patient as clinically necessary" in order "to contribute to the appropriate treatment plan for the patient and to monitor patient progress." *Id.* § 8.12(f)(5).

e. "[E]stablish and maintain a recordkeeping system that is adequate to document and monitor patient care." *Id.* § 8.12(g).

22. One of the most important aspects of OTP treatment is counseling and therapy, which enables providers to treat underlying trauma, discover the cause of patients' addiction, and prevent relapse.

23. Given its importance in treating Opioid Use Disorder, Government Healthcare Programs pay for substance abuse counseling and therapy, both in individual and group settings.

24. Defendants' clinic in Asheville, North Carolina ("the Asheville facility") has been falsifying patient group therapy records since at least September 2020.

25. The Asheville facility does not provide group therapy or counseling for patients.

26. Instead, the Asheville facility falsified—and, upon information and belief, continues to falsify—patient records by creating group therapy notes for therapy sessions that never occurred.

27. Defendants provided the Asheville facility's counselors and therapists with pre-prepared group therapy notes.

28. These notes state that group therapy sessions were held on the sidewalk outside the Asheville facility, in the lobby of the Asheville facility, or by telephone.

29. These notes often contained detailed quoted dialogue and comments from patients who purportedly participated in the group therapy session.

30. But these group therapy sessions never occurred.

31. Instead, counselors and therapists copied and reused the same falsified group therapy notes for different patients.

32. Therapists and counselors then signed these fraudulent treatment notes to make it appear that a patient participated in an interactive group therapy session.

33. On or about March 2021, Defendants formalized the falsification of their group therapy notes at the Asheville facility through a process known as bibliotherapy.

34. Bibliotherapy is a form of therapy where the therapist provides the patient with a book or article to read and then the patient comes back into the clinic to discuss what was read with the counselor.

35. Defendants began asking patients to fill out pre-printed worksheets on topics like loneliness and forgiveness.

36. However, the patients never discussed their responses with a therapist or counselor in an individual or group session.

37. Instead, Defendants continued falsifying group therapy notes, which stated that the patients participated in group therapy sessions and discussed their responses to the worksheets with therapists and/or counselors.

38. However, the resulting therapy notes were often verbatim copies or shortened versions of falsified group therapy notes previously used (and reused) by Defendants.

39. Moreover, since the beginning of the COVID-19 pandemic, Defendants have failed to perform adequate individual therapy and counseling at the Asheville facility, which leaves patients with no meaningful psychotherapy to support their recovery from addiction.

40. But the problem is not confined to the Asheville facility.

41. Relator—a Physician Assistant and the former Assistant Medical Director of the Asheville facility—learned from the Medical Director of Defendants' North Wilkesboro facility ("the North Wilkesboro facility") that Defendants were also creating falsified group therapy notes at that facility.

42. Relator and the Medical Director of the North Wilkesboro facility repeatedly notified their Clinic Directors about the fraud, but Defendants took no corrective action and, upon information and belief, did not satisfy their reporting obligations under the CIA.

43. Upon information and belief, this false and fraudulent conduct is also occurring at Defendants' facilities across the State of North Carolina and the United States.

44. Emails from the Asheville facility's Clinical Manager—Matt Lawson—indicate that, upon information and belief, Defendants Acadia and/or CRC are directing facilities to engage in this false and fraudulent conduct.

45. For example, on July 6, 2021, Matt Lawson sent an email to the Asheville facility's therapists and counselors with a false group therapy note to be used for the week.

46. Later that morning, Matt Lawson sent a follow-up email that said: "Please use the following note for the week instead of the previous one… *Corporate wants less detail*." (emphasis added).

47. The group therapy note included in that email was a shortened version of a note titled, "Relapse is Not a Sign of Failure," which had been used (and reused) by therapists and counselors since at least September 2020.

48. Upon information and belief, the Asheville facility's false and fraudulent conduct was performed at the direction of "corporate"—i.e., Defendants Acadia and CRC.

49. Upon information and belief, this method of falsifying group therapy records is a corporate policy that has been implemented in facilities owned and operated by Defendants across the country.

50. The falsified therapy notes are detailed, widespread, and violate both the law and the evidence-based standards underlying Opioid Use Disorder treatment.

51. Upon information and belief, these records are falsified in order to save time and money.

52. Upon information and belief, these records are falsified in order to give the illusion that Defendants are:

(a) Providing appropriate treatment to individuals with Opioid Use Disorder;

(b) Complying with the terms of patients' treatment plans;

(c) Complying with State and Federal law;

(d) Complying with their certification and accreditations;

(e) Complying with their provider agreements; and

(f) Complying with the CIA.

53. Upon information and belief, Defendants have actively concealed their fraudulent conduct from the United States, the State of North Carolina, and, upon information and belief, other states in order to preserve their status as providers for Government Healthcare Programs.

54. In so doing, Defendants have submitted false and fraudulent claims to Government Healthcare Programs for Opioid Use Disorder treatment.

55. When submitting those claims, Defendants expressly and/or impliedly falsely certified to Government Healthcare Programs that they were:

(a) Providing appropriate treatment to individuals with Opioid Use Disorder;

(b) Complying with the terms of patients' treatment plans;

(c) Complying with State and Federal law;

(d) Complying with their certification and accreditations;

(e) Complying with their provider agreements; and

(f) Complying with the CIA.

56. Upon information and belief, this false and fraudulent conduct is still occurring at Defendants' facilities.

57. As a result of these materially false statements, certifications, and claims, and without knowledge of their falsity, the Government Healthcare Programs have paid, and, upon information and belief, continue to pay, Defendants' false and fraudulent claims.

II. JURISDICTION AND VENUE

58. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

59. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*

60. This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3730(b) and 3732(a).

61. This Court also has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1345.

62. Additionally, the Court has jurisdiction over the state-law claims asserted in this Complaint under both 31 U.S.C. § 3732(b) and 28 U.S.C. § 1367, because the state-law claims arise from the same transaction or occurrence as the federal claims and because these claims are so related to the federal claims that they form part of the same case or controversy under Article III of the United States Constitution.

63. At all times material to this Complaint, Defendants regularly conducted substantial business within the State of North Carolina, maintained permanent employees and offices in North Carolina, and made and are making significant sales within North Carolina.

64. Defendants are thus subject to personal jurisdiction in North Carolina.

65. Venue lies in this district pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because Defendants resides in and/or has transacted business within this Court's jurisdiction, and the acts set out herein occurred in the Western District of North Carolina.

III. PARTIES

66. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

A. Governmental Plaintiffs

67. The United States of America is proceeding on behalf of its agencies, including the United States Department of Health and Human Services (“DHHS”), CMS, the Department of Defense ("DOD"), Defense Health Agency ("DHA"), and the Department of Veterans Affairs ("VA").

68. DHHS and CMS administer the Medicare program to provide health insurance for the elderly and disabled.

69. DHHS and CMS jointly administer the Medicaid program with states in order to provide health insurance to individuals whose income and resources are insufficient to pay for healthcare.

70. DOD and DHA administer the TRICARE Program.

71. The State of North Carolina is proceeding on behalf of its agencies, including the North Carolina Department of Health and Human Services ("NCDHHS").

72. NCDHHS administers the North Carolina Medicaid Program.

73. NCDHHS oversees the distribution of federal grant money for opioid treatment by distributing funds to Local Management Entities/Managed Care Organizations ("LME/MCOs").

B. Relator Wheeler

74. Relator Lisa Wheeler is a citizen and resident of North Carolina.

75. Relator Wheeler is a practicing Physician Assistant who treats patients in the areas of addiction medicine.

76. Relator Wheeler was employed as an independent contractor by Defendant ATS of North Carolina, LLC d/b/a Asheville Comprehensive Treatment Center, LLC pursuant to a Professional Services Agreement ("PSA").

77. Relator began serving as an independent contractor for Defendant ATS in January 2014.

78. Relator was the Assistant Medical Director for the Asheville Comprehensive Treatment Center.

79. On October 29, 2021, Defendant Acadia and Defendant ATS provided Relator with a thirty-day notice of termination pursuant to the PSA.

80. On or about December 4, 2021, Relator's PSA with Defendant ATS terminated.

81. Relator is an original source of this information and has voluntarily provided this information to the United States and the State of North Carolina prior to filing this Complaint.

C. Defendant Acadia Healthcare Company, Inc.

82. Defendant Acadia is a for-profit corporation organized under the laws of the State of Delaware with its principal place of business in Franklin, Tennessee.

83. At all times relevant herein, Defendant Acadia—operating independently and through its subsidiaries Defendant CRC and Defendant ATS—was doing business throughout the United States, including in the Western District of North Carolina.

84. Defendant Acadia is one of the largest providers of behavioral healthcare services and addiction treatment in the United States.

85. According to Defendant Acadia's marketing materials, it is the "largest stand-alone behavioral health company in the U.S."[1]

86. As of December 31, 2021, Defendant Acadia operated a network of 238 behavioral healthcare facilities with approximately 10,500 beds in 40 states and Puerto Rico.

[1] *About Acadia Healthcare*, Acadia Healthcare, https://www.acadiahealthcare.com/about/.

87. Defendant Acadia employs more than 20,000 employees and serves approximately 70,000 patients daily in a variety of settings, including inpatient psychiatric hospitals, specialty treatment facilities, residential treatment centers, and outpatient clinics.

88. As of December 31, 2021, Defendant Acadia owned and operated facilities in the following states: Alaska, Arizona, Arkansas, California, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

89. Upon information and belief, Defendant Acadia owns and/or operates substance abuse treatment facilities—either directly or by way of subsidiary entities—in each of these states.

90. Additionally, Defendant Acadia owns and operates facilities in Puerto Rico and the United Kingdom.

91. Defendant Acadia classifies 39% of its facilities as "specialty treatment facilities," which includes "Comprehensive Treatment Centers" ("CTCs").

92. Defendant Acadia's CTCs specialize in providing substance abuse treatment, including using MAT for individuals with Opioid Use Disorder.

93. According to its March 1, 2022, Form 10-K filed with the United States Securities and Exchange Commission, each of Defendant Acadia's "CTCs provide a range of comprehensive substance abuse treatment support services that include medical, counseling, vocational, educational, and other treatment services."[2]

[2] Form 10-K, Acadia Healthcare Company, Inc, United States Securities and Exchange Commission, at 6, *available at* https://acadiahealthcare.gcs-web.com/static-files/2c367d3a-183a-46cb-9052-2d2a78ee59e0 [hereinafter "10-K"].

94. Defendant Acadia further stated in its March 1, 2022, Form 10-K that its "behavioral therapies are delivered in an array of treatment models that may include individual and group therapy, intensive outpatient, outpatient, partial hospitalization/day treatment, road to recovery and other programs that can be either abstinent or medication assisted based."[3]

95. Defendant Acadia regularly submits, or causes to be submitted, claims for Opioid Use Disorder treatment—including, but not limited to, MAT, OTP, and OBOT services—to Government Healthcare Programs.

96. For the year ending December 31, 2021, Defendant Acadia received 49% of its revenue from Medicaid and 16% of its revenue from Medicare.

97. Moreover, upon information and belief, Defendant Acadia receives Medicaid payments from 46 states, the District of Columbia, and Puerto Rico.

98. Defendant Acadia has been a publicly traded company on NASDAQ since 2011 and generates approximately $2.3 billion in annual revenue.

99. Upon information and belief, approximately $1.495 billion of that yearly revenue (65%) comes from Medicare and Medicaid payors.

100. Because of the COVID-19 pandemic and the stressors that have caused more Americans to develop new mental health and substance use disorders, Defendant Acadia expects its revenue to continue to increase for years to come.

D. CRC Health, LLC

101. Defendant CRC is a limited liability company organized under the laws of the State of Delaware with its principal place of business in Franklin, Tennessee.

[3] *Id.*

102. Upon information and belief, Defendant CRC shares its principal place of business with Defendant Acadia and Defendant ATS in Franklin, Tennessee.

103. At all times relevant herein, Defendant CRC—operating independently and through its parent corporation, Defendant Acadia, and its subsidiary, Defendant ATS—was doing business throughout the United States, including in the Western District of North Carolina.

104. As of 2014, Defendant CRC claimed to be the largest provider of specialized behavioral healthcare services in the United States, with over 140 treatment programs and 44,000 patients per day.

105. One of Defendant CRC's primary focuses was, and still is, providing addiction treatment services and mental health services.

106. On October 29, 2014, Defendant CRC announced that it entered into an agreement to be acquired by Defendant Acadia. In this announcement, Defendant Acadia's Chairman and Chief Executive Officer, Joey Jacobs, stated:

> We expect our combination with CRC to be a great transaction for both Acadia and CRC. We believe the addiction treatment markets that CRC serves represent a very meaningful and accretive growth opportunity. As a well-established market leader, CRC will provide Acadia with an outstanding platform for growth in this fragmented market. We further expect to support CRC in taking advantage of additional growth opportunities through both our access to capital and the expertise evident in the successful long-term growth record of Acadia's management team.[4]

107. Upon information and belief, Defendant CRC is now a wholly owned subsidiary of Defendant Acadia.[5]

[4] *CRC Health Group to be Acquired by Acadia Healthcare*, PR Newswire, https://www.prnewswire.com/news-releases/crc-health-group-to-be-acquired-by-acadia-healthcare-280852262.html.

[5] *See* 10-K, *supra* note 2, at 103 (listing "CRC Health, LLC" as a subsidiary of Defendant Acadia).

108. Upon information and belief, Defendant CRC provides substance abuse treatment services for its parent corporation, Defendant Acadia, and through subsidiary companies, such as Defendant ATS.

109. Upon information and belief, Defendant CRC provides services in the following states: Alaska, Arizona, Arkansas, California, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

110. Additionally, upon information and belief, Defendant CRC also provides substance abuse treatment services in Puerto Rico and the United Kingdom.

111. Defendant CRC operates OTPs across the United States, including in the State of North Carolina.

112. Defendant CRC provides OBOT across the United States, including in the State of North Carolina.

113. Upon information and belief, Defendant CRC provides a variety of other Opioid Use Disorder services, both with and without MAT, across the United States, including in the State of North Carolina.

114. Upon information and belief, Defendant CRC regularly submits, or causes to be submitted, claims for Opioid Use Disorder treatment—including, but not limited to, MAT, OTP, and OBOT services—to Government Healthcare Programs.

115. As discussed below, many of Defendant CRC's facilities in North Carolina operate under the corporate umbrella of Defendant ATS.

116. However, upon information and belief, Defendant CRC operates similar facilities in other states by way of a variety of other subsidiary corporate entities.

117. Upon information and belief, Defendant CRC is operating under the guidance, supervision, direction, and/or control of Defendant Acadia.

E. Defendant ATS of North Carolina, LLC

118. Defendant ATS is a limited liability company organized under the laws of the State of Virginia with its principal place of business in Franklin, Tennessee.

119. Upon information and belief, Defendant ATS shares its principal place of business with Defendant CRC and Defendant Acadia in Franklin, Tennessee.

120. At all times relevant herein, Defendant ATS—operating independently and through its parent companies, Defendant Acadia and Defendant CRC—was doing business throughout the United States, including in the Western District of North Carolina.

121. Upon information and belief, Defendant ATS is a subsidiary of Defendant Acadia and Defendant CRC.[6]

122. Defendant ATS operates substance abuse treatment facilities in cities across the State of North Carolina, including, but not limited to, Asheville and North Wilkesboro.

123. According to Defendant Acadia's March 1, 2022, Form 10-K, Defendant ATS operates substance abuse treatment facilities in the following locations in North Carolina: Fayetteville, Pinehurst, Goldsboro, North Wilkesboro, Asheville, and Winston-Salem.[7]

124. Defendant ATS's Asheville facility is marketed as the "Asheville Comprehensive Treatment Center."

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[6] *See id.* at 101 (listing "ATS of North Carolina, LLC" as a subsidiary of Defendant Acadia).

[7] *See* 10-K, *supra* note 2, at 101 (listing the various "ATS of North Carolina LLC" locations).

125. The Asheville facility also does business as "Mountain Health Solutions Asheville."

126. The North Wilkesboro facility is marketed as the "North Wilkesboro Comprehensive Treatment Center."

127. The North Wilkesboro facility also does business as "Mountain Health Solutions North Wilkesboro (MHS)."

128. Relator has direct knowledge of the operations at Defendant ATS's operations at the Asheville facility and North Wilkesboro facility.

129. Upon information and belief, Defendant ATS operates other OTPs and OBOT programs across the State of North Carolina.

130. Upon information and belief, these North Carolina facilities operate in a similar manner to the Asheville and North Wilkesboro facilities, as they are operated by the same parent companies—Defendant Acadia, Defendant CRC, and Defendant ATS.

131. Upon information and belief, Defendant ATS's Managing Member is Defendant CRC.

132. Defendant ATS is the primary entity involved in face-to-face patient encounters with Defendants' patients in North Carolina.

133. Upon information and belief, Defendant ATS regularly submits, or causes to be submitted, claims for Opioid Use Disorder treatment—including, but not limited to, MAT, OTP, and OBOT services—to Government Healthcare Programs.

134. Upon information and belief, Defendant ATS is operating under the guidance, supervision, direction, and/or control of Defendant CRC and Defendant Acadia.

IV. FEDERAL AND STATE FALSE CLAIMS ACTS

135. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

A. The Federal False Claims Act

136. The FCA provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States government. 31 U.S.C. § 3729(a)(1).

137. The FCA provides, in pertinent part, that a person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (a)(1)(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
>
> (a)(1)(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
>
> . . .
>
> (a)(1)(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990[8] (28 U.S.C.

[8] By virtue of 28 C.F.R. § 85.3(a)(9), the penalty range for violations occurring on or before November 2, 2015, has increased to a minimum of $5,500 and a maximum of $11,000 per violation. The penalties have continually been adjusted for inflation, and the minimum penalty is currently $12,537 and the maximum penalty is $25,076 per violation.

> 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.

For purposes of the False Claims Act,

> the terms "knowing" and "knowingly"—(A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.

31 U.S.C. § 3729(b)(1). Moreover, the term "material" "means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

B. North Carolina False Claims Act

138. N.C. Gen. Stat. § 1-607(a) provides:

> Any person who commits any of the following acts shall be liable to the State for three times the amount of damages that the State sustains because of the act of that person. A person who commits any of the following acts also shall be liable to the State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000), as may be adjusted by Section 5 of the Federal Civil Penalties Inflation Adjustment Act of 1990, P.L. 101-410, as amended, for each violation:
>
> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
>
> (3) Conspires to commit a violation of . . . this section.

(4) Has possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less than all of that money or property.

. . .

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

139. "Knowingly" is defined as "[w]henever a person, with respect to information, does any of the following:

a. Has actual knowledge of the information.

b. Acts in deliberate ignorance of the truth or falsity of the information.

c. Acts in reckless disregard of the truth or falsity of the information.

Proof of specific intent to defraud is not required." N.C. Gen. Stat. § 1-606(4).

140. North Carolina's False Claims Act is intended "to deter persons from knowingly causing or assisting in causing the State to pay claims that are false or fraudulent and to provide remedies in the form of treble damages and civil penalties when money is obtained from the State by reason of a false or fraudulent claim." N.C. Gen. Stat. § 1-605(b).

C. North Carolina Medical Assistance Provider False Claims Act

141. N.C. Gen. Stat. § 108A-70.12 makes it unlawful for any provider of medical assistance under the Medical Assistance Program to:

(1) Knowingly present, or cause to be presented to the Medical Assistance Program a false or fraudulent claim for payment or approval; or

(2) Knowingly make, use, or cause to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Medical Assistance Program.

142. A provider of medical assistance who violates this statute is subject to civil penalties of between $5,000 and $10,000 as well as treble damages. N.C. Gen. Stat. § 108-70.12(b).

V. GOVERNMENT HEALTHCARE PROGRAMS AND OPIOID USE DISORDER

143. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

A. The Opioid Crisis in America

144. Opioids have been used for thousands of years to treat various medical conditions, including pain, diarrhea, and coughs.

145. Most commonly, opioids are used for pain relief.

146. Common opioids include codeine, oxycodone, hydrocodone, hydromorphone, morphine, heroin, and fentanyl.

147. For many years, opioids were commonly prescribed to individuals with acute and chronic pain.

148. Often, patients were not provided any information about the addictive properties of opioids.

149. Some opioid medications contain a combination of an opioid and over-the-counter pain medication, like acetaminophen (i.e., Vicodin and Percocet), aspirin (i.e., Percodan), or ibuprofen (i.e., Vicoprofen).

150. While these combination medications are effective for individuals with mild to moderate pain, the presence of over-the-counter medications with their own negative side effects, such as ulcers or liver damage, limits their efficacy for individuals in severe pain.

151. In response to this problem, pharmaceutical companies developed much stronger opioid medications like Oxycontin (i.e., oxycodone) and Opana (i.e., oxymorphone).

152. Pharmaceutical companies aggressively marketed these medications, frequently promoting the pills as non-addictive if used as prescribed and claiming that proprietary extended-release formulations were unable to be abused.

153. Tragically, the pills were, in fact, addictive and the "abuse deterrent" formulations could easily be circumvented.

154. Individuals who obtained these medications from a doctor or through diversion often took excessive doses on a regular basis which, in turn, increased their tolerances.

155. The result was, in many ways, inevitable: widespread addiction.

156. In recent years, physicians' prescribing habits have changed, and opioids are prescribed less frequently and in much lower doses.

157. While this led to fewer pills in peoples' medicine cabinets and, thus, fewer pills subject to illegal diversion, many individuals were left with severe addictions.

158. Some longtime patients were rapidly tapered to lower doses. Others were simply cut off by their doctors.

159. This, in turn, led to many individuals suffering from opioid withdrawal.

160. Early withdrawal symptoms typically begin within 24 hours after a person stops using opioids, though they can begin much earlier in severely opioid dependent individuals.

161. People going through opioid withdrawal suffer from symptoms ranging from muscle aches and anxiety to diarrhea, nausea, and high blood pressure.

162. Individuals in opioid withdrawal know that there is one sure-fire cure to stop the pain and misery: more opioids.

163. But the decreased supply of prescribed opioids made that difficult, if not impossible, for many people who were tapered or cutoff by their doctors.

164. Again, the result was inevitable: increased use of non-pharmaceutical opioids such as heroin and fentanyl.

165. In recent years, opioid overdose deaths have increased exponentially.

166. One of the primary causes of this increases is the proliferation of illicit fentanyl and fentanyl analogues.

167. It is difficult to quantify the devastation that has resulted from this, but the statistics that are available are staggering:

(a) "In 2017, health care providers across the [United States] wrote more than 191 million prescriptions for opioid pain medication—a rate of 58.7 prescriptions per 100 people."[9]

(b) "Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them."[10]

(c) "Between 8 and 12 percent of people using an opioid for chronic pain develop an opioid use disorder."[11]

(d) "An estimated 4 to 6 percent who misuse prescription opioids transition to heroin."[12]

(e) Nearly 841,000 people have died from a drug overdose since 1999. More than 70% of these deaths in 2019 involved an opioid.[13]

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[9] *7 Staggering Statistics About America's Opioid Epidemic*, ChoosePT, https://www.choosept.com/resources/detail/7-staggering-statistics-about-america-s-opioid-epi. [hereinafter, "*Stats*"].

[10] *Opioid Overdose Crisis*, National Institute on Drug Abuse, https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis [hereinafter, "*Crisis*"].

[11] *Id.*

[12] *Id.*

[13] *The Drug Overdose Epidemic: Behind the Numbers*, Centers for Disease Control and Prevention, https://www.cdc.gov/opioids/data/index.html.

(f) In 2019 alone, nearly 50,000 people in the United States died from opioid-related overdoses.[14]

(g) "The CDC estimates the total economic burden of prescription opioid misuse in the [United States] is $78.5 billion a year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement."[15]

(h) "During 2020, 28 states saw drug overdose deaths increase by more than 30 percent, amid the social isolation and economic stress of the pandemic."[16]

(i) In fact, data released by the CDC "show[s] that drug overdose deaths reached a record high of 93,331 in 2020."[17] This is an increase of more than 20,000 deaths from 2019.

B. Opioid Use Disorder and Treatment

168. In 2017, the U.S. Department of Health and Human Services ("HHS") declared a public health emergency due to the widespread misuse and overdose-related deaths caused by opioids.

169. In 2017, to combat the epidemic, HHS issued over $800 million in grants to support the treatment and recovery of opioid addiction.

170. Between fiscal year 2016 and 2019, HHS provided more than $9 billion in grants to states, Native American tribes, and local communities to combat the opioid crisis.

171. This effort is showing some success, and Opioid Use Disorder treatment has spread throughout the United States.

172. There are currently more than 14,000 substance abuse facilities in the United States.

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[14] *Crisis*, *supra* note 10.

[15] *Stats*, *supra* note 9.

[16] *The Drug Overdose Toll in 2020 and Near-Term Actions for Addressing It*, The Commonwealth Fund, https://www.commonwealthfund.org/blog/2021/drug-overdose-toll-2020-and-near-term-actions-addressing-it.

[17] *Id.*

173. One of the most effective treatments for individuals with Opioid Use Disorder is MAT.

174. Opioid Use Disorder treatment providers combine MAT with other modalities, such as behavioral therapy, as part of a comprehensive treatment plan.

175. Opioid Use Disorder treatment can be provided in a variety of settings, including inpatient, intensive outpatient, OTPs, and OBOT.

176. OTPs are treatment programs that dispense medication and provide counseling and other recovery support on-site.

177. OBOT refers to outpatient Opioid Use Disorder treatment provided in a setting other than a licensed OTP.

178. One of the most important aspects of OTPs and OBOT is group and/or individual therapy, which is provided in conjunction with MAT.

179. Three drugs are approved by the FDA for the treatment of Opioid Use Disorder: Methadone, Buprenorphine, and Naltrexone.

180. **Methadone** is administered daily as either a tablet or oral concentrate in order to control withdrawal symptoms and cravings.

181. Methadone is a synthetic opioid agonist that is used either for short periods of time to detoxify opioid users or for a longer period of time as maintenance therapy.

182. Some patients transition to Methadone from their opioid of choice and taper their dose to become opioid free while others take Methadone as a long-term, daily replacement in order to prevent withdrawal and relapse.

183. Methadone patients must receive their medication from OTPs, as physicians are not permitted to prescribe Methadone for Opioid Use Disorder outside of the confines of an OTP.

184. Methadone is generally dispensed daily by OTPs in order to prevent diversion, monitor a patient's response and any potential drug interactions, facilitate the provision of related services, such as individual and/or group therapy, and instill structure in the lives of individuals in recovery.

185. Many clinics do allow patients to earn "take home" privileges after a patient demonstrates compliance with her opioid treatment program.

186. Methadone is a Schedule II controlled substance, which means it is subject to the strictest prescribing and handling requirements of all medications on the American market.

187. **Buprenorphine** is an opioid that is used to treat Opioid Use Disorder.

188. Buprenorphine is available in several formulations: a tablet or strip that is used under the tongue (i.e., sublingual) or in the cheek (i.e., buccal), an intravenous or subcutaneous injection, a skin patch, or an implant.

189. Sublingual/buccal Buprenorphine is the most common formulation, either as a standalone substance (i.e., Subutex) or in combination with naloxone (i.e., Suboxone).[18]

190. Unlike Methadone, patients must wait a defined period of time prior to starting Buprenorphine, as its high binding affinity to certain opioid receptors can displace other opioids with lower binding affinities, which precipitates acute opioid withdrawal in the user.

191. Therefore, patients typically go through Buprenorphine induction under the supervision of a medical professional.

192. Buprenorphine can be dispensed by OTPs.

[18] Naloxone is an opioid antagonist with a high bioavailability when injected that is combined with Buprenorphine to discourage intravenous abuse. Naloxone will put an individual into acute opioid withdrawal if the formulation is injected.

193. However, unlike Methadone, Buprenorphine can be prescribed by healthcare providers as a part of OBOT.

194. Buprenorphine is a Schedule III controlled substance.

195. **Naltrexone** (Brand Name: Vivitrol) is an extended-release injectable suspension, which is administered in an intramuscular injection.

196. Naltrexone is an opioid antagonist, which means that it blocks the activation of opioid receptors.

197. Therefore, rather than controlling withdrawal symptoms and cravings, it prevents a user from achieving euphoria or other positive effects when using an opioid.

198. Naltrexone is generally administered approximately every four weeks.

C. Medicare Coverage for Opioid Use Disorder

199. In 1965, Congress enacted the Medicare program under Title XVIII of the Social Security Act, creating the federal health insurance program for Americans 65 years or older, certain individuals with disabilities, and those afflicted with end-stage renal disease.

200. Medicare is funded through trust fund accounts held by the U.S. Treasury and supported by American taxpayers.

201. The Secretary of HHS has overall responsibility for the administration of Medicare. Within HHS, the responsibility for the administration of Medicare has been delegated to CMS.

202. Health care providers must have a National Provider Identifier ("NPI") number prior to enrolling in Medicare.

203. Federal statutes and regulations require providers to comply with and be knowledgeable of applicable regulations, statutes, and guidelines in order to be reimbursed by Medicare. 42 C.F.R. § 424.516(a)(1), (2).

204. Medicare only covers medically necessary items or services, excluding from coverage "any expenses incurred for items or services […] which […] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

205. In order to submit a claim to Medicare, institutional providers (including hospitals and freestanding OTP facilities) use the CMS Form 1450 claims form or the electronic equivalent.

206. The Form 1450 requires the provider to, *inter alia*, detail patient information, insurance information, date of treatment, provider information, and other relevant information to the patient's treatment and claim.

207. The back of the Form 1450 states: "Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete . . . [and] [t]hat the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts."

208. Additionally, the back of the Form 1450 states, in bold print: **"THE SUBMITTER OF THIS FORM UNDERSTANDS THAT MISREPRESENTATION OR FALSIFICATION OF ESSENTIAL INFORMATION AS REQUESTED BY THIS FORM MAY SERVE AS THE BASIS FOR CIVIL MONETARY PENALTIES AND ASSESSMENTS AND MAY UPON CONVICTION INCLUDE FINES AND/OR IMPRISONMENT UNDER FEDERAL AND/OR STATE LAW(S)."**

209. Similarly, professional providers submit claims to Medicare on the HCFA 1500 claims form ("Form 1500").

210. The Form 1500 requires the provider to, *inter alia*, detail patient information, insurance information, date of treatment, provider information, and other relevant information to the

patient's treatment and claim.

211. The back of the Form 1500 states, in bold print, **"Notice: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."**

212. The Form 1500 requires the signature of the provider of the medical or surgical services.

213. By signing the Form 1500, the provider "certif[ies] that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations."

214. As Medicare providers, Defendants are obligated to understand and certify their compliance with all applicable Medicare laws, regulations, and program instructions as a condition of payment of Medicare reimbursements.

215. Healthcare providers are prohibited from knowingly presenting or causing to be presented claims that represent a pattern of items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. 42 U.S.C. §§ 1320a-7a(a)(1); 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).

1. Opioid Treatment Programs, SAMHSA Certification, and Accreditation

216. Federal law sets forth treatment standards for OTPs, including a requirement that counseling and other nondrug services be provided.[19] *See* 42 C.F.R. § 8.12.

217. In order to participate in the Medicare program and receive the bundled billing rates described below, an OTP must: (1) Be enrolled in the Medicare program; (2) have in effect a certification by SAMHSA for the OTP; (3) be accredited by an accrediting body approved by SAMHSA; and (4) have in effect a provider agreement with CMS.

218. Under 42 C.F.R. § 8.11, an OTP "must be the subject of a current, valid certification from SAMHSA to be considered qualified . . . to dispense opioid drugs in the treatment of opioid use disorder."

219. SAMHSA is a governmental agency that is a branch of HHS. SAMHSA "leads public health efforts to advance the behavioral health of the nation."[20]

220. SAMHSA's "mission is to reduce the impact of substance abuse and mental illness in America's communities."[21]

221. In order to obtain SAMHSA certification, "an OTP must meet the Federal opioid treatment standards in [42 C.F.R.] § 8.12, must be the subject of a current, valid accreditation by

[19] The OTP regulations allow counseling or individual/group therapy by "two-way interactive audio-video communication technology" to the extent authorized under State law and as clinically appropriate. *See* 42 C.F.R. §§ 410.67(b)(3), (4). In light of the COVID-19 pandemic, the regulations allow counseling or individual/group by "audio-only telephone calls" in "cases where audio/video communication technology is not available to the beneficiary . . . ." *See id.*

[20] *About Us*, SAMHSA, https://www.samhsa.gov/about-us.

[21] *Id.*

an accreditation body or other entity designated by SAMHSA, and must comply with any other conditions for certification established by SAMHSA." *Id.* § 8.11(a)(2).

222. The SAMHSA certification application must contain a statement that the OTP will, *inter alia*, "operate in accordance with Federal opioid treatment standards and approved accreditation elements." *Id.* §§ 8.11(b)(6), (f)(7).

223. Compliance with these standards is, thus, an express condition for SAMHSA certification. *See id*. § 8.11(f)(7).

224. 42 C.F.R. § 8.12 provides an extensive list of Federal opioid treatment standards.

225. The following is non-exhaustive list of those administrative, recordkeeping, and counseling requirements that must be provided by an OTP to obtain, and maintain, its certification (and, as detailed below, its participation in Medicare):

(a) "An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations." *Id.* § 8.12(b).

(b) "Each person engaged in the treatment of opioid use disorder must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions." *Id.* § 8.12(d).

(c) "OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients." *Id*. § 8.12(f)(1).

(d) "OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress." *Id.* § 8.12(f)(5)(i).

(e) "OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal

and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid use disorder." *Id.* § 8.12(g)(1).

226. Each patient accepted for treatment at an OTP must first be assessed initially and periodically throughout her treatment "to determine the most appropriate combination of services and treatment." *Id.* § 8.12(f)(4).

227. "The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical psychosocial, economic, legal, or other supportive services that a patient needs." *Id.*

228. "The treatment plan also must identify the frequency with which these services are to be provided." *Id.*

229. The treatment plan must be reviewed and updated to reflect the patient's evolving needs.

230. In addition to SAMHSA certification, OTPs must be accredited by an accrediting body approved by SAMHSA.

231. SAMHSA has approved at least six accrediting bodies in order to "ensure that OTPs meet specific, nationally accepted standards for providing [MAT] . . . .": (1) CARF International; (2) Council on Accreditation; (3) The Joint Commission; (4) Missouri Department of Mental Health, Division of Behavioral Health; (5) National Commission on Correctional Health Care; and (6) Washington State Department of Health, Health Services Quality Assurance.[22]

[22] *Approved Accreditation Bodies*, SAMHSA, https://www.samhsa.gov/medication-assisted-treatment/become-accredited-opioid-treatment-program/approved-accreditation-bodies.

232. Upon information and belief, these accrediting bodies require OTP providers to implement, *inter alia*, policies and procedures for regulatory compliance, treatment plans for individual patients, and services in addition to the simple administration of MAT.

233. Put differently, the accrediting agencies require OTP providers to do more than simply administer Methadone, Buprenorphine, and Naltrexone.

234. As detailed below, Defendants, acting in concert with one another, represent to governmental payors that they comply with the Federal opioid treatment standards set forth in 42 C.F.R. § 8.12 and are in compliance with the SAMHSA certification standards, accreditation requirements, and provider agreements.

235. However, upon information and belief, Defendants' false and fraudulent conduct violates their SAMHSA certification, accreditation, the Federal OTP standards, and their provider agreements with CMS.

2. The SUPPORT Act and Bundled Billing

236. In 2018, Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the "SUPPORT Act").

237. In response, CMS promulgated a rule which implemented certain provisions of the SUPPORT Act and changed the way that Medicare covers opioid treatment.

238. The rule would have permitted providers to bill for bundled services.

239. Put differently, rather than billing for individual services provided under various parts of Medicare, providers would be permitted to bill for a bundle of services on a weekly basis.

240. When promulgating the proposed rules and regulations applicable to bundled billing, CMS assumed that a typical patient would receive "one substance use counseling session, one

individual therapy session, and one group therapy session per week and one toxicology test per month." 84 F.R. 62568-01, 62641 (Nov. 15, 2019).

241. Under this initial proposal, providers would only be able to bill Medicare for a bundle of treatment services, like the group of services listed above, if the beneficiary received at least 51% of the services in the patient's treatment plan. *See id.*

242. Some commenters stated that "it would be cumbersome to implement and would require far more frequent updating of the treatment plan than is typical, especially since the frequency of services delivered can vary significantly from week to week." *Id.*

243. CMS responded by stating: "In the interest of combating the opioid crisis and in the best interest of beneficiaries our goal is to minimize barriers to OTPs enrolling in Medicare and beginning to furnish services to Medicare beneficiaries." *Id.* at 62642.

244. Therefore, rather than requiring at least 51% of the services in a beneficiary's treatment plan be provided, CMS adopted a rule that only required one Opioid Use Disorder treatment service be provided during a weekly episode of care in order to bill Medicare for the entire weekly bundle of services.

245. CMS emphasized, however, that it would "be monitoring for abuse given this lower threshold for billing for full weekly bundled payment." *Id.* (emphasis added).

246. One of the most important safeguards to preventing fraud is ensuring that providers comply with the SAMHSA certification and accreditation requirements and the Federal OTP standards outlined above.

247. While CMS permits providers to bill for a bundle of services without necessarily providing a majority of the services in a patient's treatment plan every week, the regulatory re-

quirements that OTPs are required to abide by—namely the OTP regulations and SAMHSA certification and accreditation—*already* require that counseling and other services in a patient's treatment plan be provided as a precondition to a provider's ability to participate in Medicare.

248. The bundled payment system discussed above has now been codified in the Code of Federal Regulations.

249. As of January 1, 2020, the SUPPORT Act requires that CMS pays a bundled payment rate for Opioid Use Disorder treatment services furnished by an OTP to individuals. *See* 42 C.F.R. § 410.67(d).

250. The regulation defines an Opioid Use Disorder treatment service to include one of the following items or services:

> (1) Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration . . . for use in treatment of opioid use disorder.
>
> (2) Dispensing and administration of opioid agonist and antagonist treatment medications, if applicable.
>
> (3) Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency . . . where audio/video communication technology is not available to the beneficiary, the counseling services may be furnished using audio-only telephone calls if all other applicable requirements are met.
>
> (4) Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency . . . where audio/video communication technology is not available to the beneficiary, the therapy services may be furnished using audio-only telephone calls if all other applicable requirements are met.
>
> (5) Toxicology testing.

(6) Intake activities, including initial medical examination services . . . and initial assessment services . . . .

(7) Periodic assessment services . . . that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During the Public Health Emergency . . . in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

(8) Opioid antagonist medications that are approved by the Food and Drug Administration . . . for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication.

42 C.F.R. § 410.67(b).

251. An OTP must furnish "[a]t least one OUD treatment service" described in paragraphs (1) through (5) of the above list in order to submit a bill for the bundled payment.

252. The regulation outlines two types of bundled payments: (1) a "bundled payment for episodes of care in which a medication is provided"; and (2) "a bundled payment for episodes of care in which no medication is provided . . . ." *Id.* § 410.67(d)(2).

253. When a drug is provided, the bundled payment rate is heavily based on the drug component of the treatment provided in combination with the payment rate for the nondrug component of services. *See id.* § 410.67(d)(2).

254. The non-drug component of the bundled payment rate is based on the "sum" of: (A) the physician fee schedule rates for (1) psychotherapy (30 minutes with patient); (2) group psychotherapy; (3) alcohol and/or substance abuse assessment and intervention at the non-physician rate; (4) injectable medication administration (if applicable); and (5) the insertion, removal, or insertion and removal of an implantable medication (if applicable); (B) the average dispensing fees for oral medication "under state Medicaid programs" (if applicable); and (C) one-fourth of the 2019 clinical lab fee schedule for a presumptive and definitive drug test. *Id.* § 410.67(d)(2)(ii).

255. This rate is based on a weekly bundle of services, known as an "episode of care." *See id.* § 410.67(b).

256. Upon information and belief, at Defendant ATS's facilities, the weekly session goes Wednesday to Wednesday.

257. If a patient requires more counseling, including individual or group therapy than the amount in the plan or bundle, then the OTP can bill Medicare for add-on codes to increase the amount of payment it receives in the bundled payment rate. *See id.* § 410.67(d)(4)(i)(A).

258. The codes that are used by Medicare for bundled OTP services include G2067, G2068, G2069, G2070, G2071, G2072, G2073, G2074, and G2075. The following is a list of each code and the payment amount for the drug and nondrug portion of the bundled payment.

(a) HCPCS code G2067: Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $37.38
   - **Nondrug Cost:** $178.29
   - **Total Cost:** $215.67

(b) HCPCS code G2068: Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $78.79
   - **Nondrug Cost:** $178.29
   - **Total Cost:** $257.08

(c) HCPCS code G2069: Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $1,695.09
   - **Nondrug Cost:** $184.96
   - **Total Cost:** $1,880.05

(d) HCPCS code G2070: Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $4,950
   - **Nondrug Cost:** $422.26
   - **Total Cost:** $5,372.26

(e) HCPCS code G2071: Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $0
   - **Nondrug Cost:** $422.40
   - **Total Cost:** $422.40

(f) HCPCS code G2072: Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $4,950
   - **Nondrug Cost:** $649.10
   - **Total Cost:** $5,599.10

(g) HCPCS code G2073: Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $1,264.26
   - **Nondrug Cost:** $184.96
   - **Total Cost:** $1,449.22

(h) HCPCS code G2074: Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
   - **Drug Cost:** $0
   - **Nondrug Cost:** $167.42
   - **Total Cost:** $167.42

(i) HCPCS code G2075: Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance

> use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).[23]

259. The code that a provider bills depends on the type of drug that was given to the patient.

260. While the drug cost significantly outsizes the nondrug cost for injectable and implantable MAT drugs, the nondrug cost is higher for the two most commonly prescribed MAT drugs—oral methadone and oral buprenorphine.

261. Defendants are paid for OTP services by Medicare and other Government Healthcare Programs using these "bundled" codes.

D. Medicaid Coverage for Opioid Use Disorder

262. The Medicaid Program is a health insurance program for low-income individuals and families and is jointly funded by the federal government and states.

263. States are not required to participate in the Medicaid program, but if they choose to, they must abide by the Medicaid requirements.

264. All states, including the State of North Carolina, participate in the Medicaid program.

265. In order to be eligible for federal assistance under the Medicaid program, a state must have a plan for medical assistance that has been approved by the Secretary of HHS. 42 U.S.C. § 1396a(a).

266. When the Secretary of HHS approves a state's plan, the state then administers the various medical assistance programs under the Medicaid umbrella and the federal government

[23] This Code is a placeholder for new drugs that are not specified in existing codes. Therefore, there is no fixed cost associated with the Code at this time.

provides grants to the state to reimburse them for medical services provided. *Id.*

267. The federal government pays states for a specified percentage of program expenditures, determined by the Federal Medical Assistance Percentage ("FMAP"). CMS also helps to administer this program.

268. Before providers may submit claims, DHHS requires that providers satisfy an enrollment process.

269. Providers enrolled in Medicaid must follow all Medicaid guidelines.

270. When submitting a claim for payment, providers must certify that they are complying with all Medicaid guidelines and regulations and federal and state law.

1. Medicaid Coverage for Opioid Use Disorder and Treatment

271. Medicaid provides health coverage for individuals with Opioid Use Disorder.

272. The Affordable Care Act expanded Medicaid coverage for addiction treatment.

273. Many states further expanded Medicaid coverage in 2019 for behavioral health services, such as mental health and substance abuse.

274. To combat the opioid epidemic and in an effort to increase the availability of Medicaid benefits for addiction treatment, many states reduced administrative utilization controls.

275. On December 30, 2020, CMS issued a State Health Official letter, SHO# 20-005, which outlined the changes in federal law related to Medicaid's provision of MAT and coverage of OTP-related services.

276. The introductory paragraph to the letter states: "To increase access to medication-assisted treatment (MAT) for opioid use disorders (OUD), section 1006(b) of the SUPPORT Act

requires states to provide Medicaid coverage of certain drugs and biological products, and related counseling services and behavioral therapy."[24]

277. These changes were reflected in the Medicaid statutes.

278. For example, 42 U.S.C. § 1396(ee)(1) defines MAT to mean: **(A)** "all drugs approved under section 355 of Title 21, including methadone, and all biological products licensed under section 262 of this title to treat opioid use disorders; and **(B)** includes, with respect to the provision of such drugs and biological products, counseling services and behavioral therapy."

279. Medicaid Programs are now required to cover MAT services, including medication, counseling services, and behavioral therapy.

280. CMS's SHO letter includes the following mandate:

> To address the full scope of patients' treatment needs, section 1905(ee)(1) defines the required MAT benefit as including counseling services and behavioral therapy related to the drugs and biologicals covered under the new mandatory benefit. While states have flexibility to specify which counseling services and behavioral therapy they will include in the new mandatory benefit, states that already cover MAT successfully often cover a range of effective behavioral health services for beneficiaries with OUD receiving MAT, including the following:
>
> - Individual/Group Therapy generally helps patients identify treatment goals and potential solutions to problems that cause emotional stress; seeks to restore communication and coping skills; strengthens self-esteem; and promotes behavior change and optimal mental health. Cognitive behavioral therapy is a type of therapy that has been shown to be successful in treating individuals with OUD.
>
> - Peer Support Services are typically understood to be services in which a qualified peer support provider (also called a recovery coach or peer recovery support specialist) assists individuals with their recovery from substance use disorders, including OUD. Peer support services can also be offered in relation to co-occurring mental disorders and OUD. Services can include counseling on coping with symptoms and navigating early stages of the recovery process; modeling appropriate behavior, skills, and communication; engagement with a supportive community of recovering peers; and helping

[24] https://www.medicaid.gov/federal-policy-guidance/downloads/sho20005.pdf [hereinafter, "SHO Letter"].

the person access community resources. CMS has issued guidance that addresses requirements for peer support providers.

- Crisis Intervention Services are typically provided to immediately reduce or eliminate the risk of physical or emotional harm. Services can include evaluation, triage, and access to services, and treatment to effect symptom reduction, harm reduction, and/or safe transition of individuals in acute crisis to the appropriate level of care for stabilization.[25]

281. The SHO letter also stated that "Federal regulation requires patients who receive treatment in an OTP to receive access to medical counseling, vocational, educational, and other assessment and treatment services, in addition to prescribed medication."[26]

2. North Carolina Medicaid

282. NC Department of Health and Human Services ("NC DHHS") manages the Medicaid program in North Carolina.

283. There are approximately two million Medicaid beneficiaries in North Carolina.

284. North Carolina did not adopt the Affordable Care Act's Medicaid expansion.

285. NC DHHS provides coverage for OTP services, OBOT, and other Opioid Use Disorder treatments.

286. NC DHHS provides coverage for individual and group therapy for individuals with Opioid Use Disorder.

287. On April 25, 2019, CMS notified NC DHHS that its proposed Substance Use Disorder ("SUD") protocol was approved.[27]

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[25] *Id.* at 4.

[26] *Id.* at 6.

[27] https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nc/Medicaid-Reform/nc-medicaid-reform-demo-sud-imp-plan-prtcl-20190425.pdf.

288. That protocol includes coverage for individuals receiving office-based OTP services.

289. It does not appear that NC DHHS has issued a formal protocol or policy implementing the SUPPORT Act's requirements that OTP services be covered by Medicaid.

290. Upon information and belief, NC DHHS has been providing coverage for OTP services prior to the SUPPORT Act.

291. However, because the State of North Carolina participates in the Medicaid Program, it was required to start covering OTP services no later than October 1, 2020, including "counseling services and behavioral therapies associated with provision of the required drug and biological coverage."[28]

292. Upon information and belief, the State of North Carolina is currently complying with the SUPPORT Act's mandate that Medicaid cover OTP services.

293. Upon information and belief, NC DHHS has implemented a policy for OBOT—Medicaid Clinical Coverage Policy 1A-41 ("OBOT Policy").[29]

294. NC DHHS covers OBOT "when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;

b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and

[28] SHO Letter, *supra* note 24, at 7.

[29] NC Medicaid, Clinical Coverage Policy 1A-41, https://files.nc.gov/ncdma/documents/files/1A-41_6.pdf.

c. [t]he procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider."[30]

295. The OBOT Policy further states that it covers OBOT services when **all** the following components are met: diagnosis and initial evaluation, initial laboratory testing, psychosocial treatment modalities, informed consent, treatment plan, treatment contract, and prescription drug monitoring."[31]

296. The OBOT Policy contains detailed requirements for each of these categories of treatment/services.

297. For example, NC Medicaid "require[s] a minimum of once monthly individual or group therapy sessions during the induction and stabilization phases of treatment conducted by a behavioral health professional licensed to treat substance use disorders . . . ."[32]

298. The OBOT Policy also requires that providers create an individualized treatment plan for beneficiaries.

299. Importantly, the OBOT Policy differentiates between OBOTs and OTPs, and makes clear that an OTP is a higher level of care that is subject to the Federal requirements outlined above—i.e., SAMHSA certification, accreditation by a SAMHSA accrediting body, and compliance with all Federal OTP regulations.[33]

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[30] *Id.* at 5.

[31] *Id.* at 6.

[32] *Id.* at 8.

[33] *See id.* at 1–3.

300. In order to bill Medicaid for OBOT or OTP services, providers (both physicians and non-physicians) must complete a certification process through NCTracks to become "Medicaid certified."

301. As part of this process, providers must also complete training on fraud, waste, and abuse.

302. Medicaid also directly contracts with LME/MCOs to manage the care of Medicaid beneficiaries who receive services for mental health, developmental disabilities, or substance use disorders.

303. Claims for Opioid Use Disorder treatment are submitted through these LME/MCOs.

304. Upon information and belief, Defendants have contracts with NC DHHS and LME/MCOs.

305. Upon information and belief, the contracts provide, among other things, that Defendants will comply with federal and state laws, including the federal False Claims Act and the North Carolina False Claims Act, and regulations concerning the provision or billing of Medicaid-reimbursable or State-funded services.

E. TRICARE Coverage for Opioid Use Disorder

306. TRICARE (formerly "CHAMPUS") is a medical benefits program established by federal law. *See* 10 U.S.C. § 1071–1110b.

307. TRICARE provides healthcare benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

308. TRICARE is administered by the DOD and the DHA.

309. Upon information and belief, Defendants are participating providers in the TRICARE program.

310. Upon information and belief, Defendants' provider agreements and/or contracts with TRICARE provide that Defendants will comply with federal and state laws, including the federal False Claims Act and the North Carolina False Claims Act, and regulations concerning the provision or billing of TRICARE eligible services.

311. TRICARE covers only medically necessary inpatient and outpatient care.

312. TRICARE provides coverage for OTP services.

313. TRICARE regulations define "Opioid Treatment Program" as follows:

> [OTPs] are service settings for opioid treatment, either free standing or hospital based, that adhere to the Department of Health and Human Services' regulations at 42 C.F.R. part 8 and use medications indicated and approved by the Food and Drug Administration. Treatment in OTPs provides a comprehensive, individually tailored program of medication therapy integrated with psychosocial and medical treatment and support services that address factors affecting each patient, as certified by the Center for Substance Abuse Treatment (CSAT) of the Department of Health and Human Services' Substance Abuse and Mental Health Services Administration. Treatment in OTPs can include management of withdrawal symptoms (detoxification) from opioids and medically supervised withdrawal from maintenance medications. Patients receiving care for substance use and co-occurring disorders care can be referred to, or otherwise concurrently enrolled in, OTPs.

32 C.F.R. § 199.2.

314. "Providers seeking payment from the Federal Government through programs such as [TRICARE] have a duty to familiarize themselves with, and comply with, the program requirements." 32 C.F.R. § 199.9(a)(4).

315. TRICARE regulations also provide that it may deny payment in "abuse situations." 32 C.F.R. § 199.9(b).

316. TRICARE regulations define "abuse situations" to include, *inter alia*, "[a] pattern of claims for services which are not medically necessary or, if medically necessary, not to the

extent rendered"; "[c]are of inferior quality"; and "[f]ailure to maintain adequate medical or financial records." *Id.*

317. To avoid abuse situations, providers are obligated to provide services and supplies under TRICARE that are: "Furnished at the appropriate level and only when and to the extent medically necessary . . . ; of a quality that meets professionally recognized standards of health care; and, supported by adequate medical documentation as may reasonably be required under this part . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care." *Id.*

318. "[A]buse situations under [TRICARE] are a sufficient basis for denying all or any part of [TRICARE] cost-sharing of individual claims." *Id.*

319. TRICARE regulations also define "fraud" as:

> (1) a deception or misrepresentation by a provider, beneficiary, sponsor, or any person acting on behalf of a provider, sponsor, or beneficiary with the knowledge (or who had reason to know or should have known) that the deception or misrepresentation could result in some unauthorized [TRICARE] benefit to self or some other person, or some unauthorized [TRICARE] payment, or (2) a claim that is false or fictitious, or includes or is supported by any written statement which asserts a material fact which is false or fictitious, or includes or is supported by any written statement that (a) omits a material fact and (b) is false or fictitious as a result of such omission and (c) is a statement in which the person making, presenting, or submitting such statement has a duty to include such material fact.

32 C.F.R. § 199.2.

320. TRICARE regulations contain examples of situations which are "presumed to be fraud," including: "Submitting [TRICARE] claims (including billings by providers when the claim is submitted by the beneficiary) for services, supplies, or equipment not furnished to, or used by, [TRICARE] beneficiaries"; "[m]isrepresentations of dates, frequency, duration, or description of services rendered, or of the identity of the recipient of the services or the individual who rendered

the services"; and "[s]ubmitting falsified or altered [TRICARE] claims or medical or mental health patient records which misrepresent the type, frequency, or duration of services or supplies or misrepresent the name(s) of the individual(s) who provided the services or supplies." 32 C.F.R. § 199.9(c).

F. Department of Veterans Affairs Treatment of Opioid Use Disorder

321. The VA operates hundreds of medical centers and outpatient clinics throughout the country.

322. The Veterans Health Administration ("VHA") is the component of the VA that implements and manages these facilities so that veterans can receive comprehensive medical care.

323. According to SAMHSA, in 2019, 3.9 million veterans "had a mental illness and/or substance use disorder . . . ."[34]

324. Many of those veterans suffer from Opioid Use Disorder.

325. The VA provides Opioid Use Disorder treatment to veterans.

326. As of 2018, the VA operated more than 30 OTPs across the country.

327. However, most VA facilities do not have on-site OTPs.

328. For facilities and communities without VA run OTPs, the VA often contracts with outside OTPs to provide treatment to veterans.

329. According to VHA Handbook 1160.04:

> VA medical facilities are required to provide treatment for opioid dependence using either an OTP or an outpatient treatment plan that includes the partial agonist bu-

[34] *2019 National Survey on Drug Use and Health: Veteran Adults*, SAMHSA at 4 (September 2020), https://www.samhsa.gov/data/sites/default/files/reports/rpt31103/2019NSDUH-Veteran/Veterans%202019%20NSDUH.pdf.

prenorphine. VA medical facilities without OTPs are required to make arrangements for access to methadone treatment for eligible Veterans if buprenorphine treatment is not clinically effective.[35]

330. OTPs that provide services to VA patients are governed by the federal regulations, accreditation, and certification requirements in 42 C.F.R. Part 8.

G. Federal Grant Funding for Treatment of Opioid Use Disorder – 21st Century Cures Act

331. In 2016, Congress passed the 21st Century Cures Act ("the Cures Act").

332. The Cures Act made SAMHSA funding available to states to help combat the opioid crisis.

333. SAMHSA awarded $485 Million in funding to all 50 states.

334. SAMHSA created a State Targeted Response ("STR") project to provide funding to states to help fund treatment and other abatement efforts.

335. In May 2017, North Carolina was awarded more than $31 million through SAMHSA's STR project.

336. On May 1, 2017, NC DHHS received $15,586,724 and was required to use at least 80% of those funds for outreach, engagement, treatment, and recovery services.

337. NC DHHS expected to use those funds to serve at least 1,460 individuals during the first year of grant funding.

338. NC DHHS distributed this money to LME/MCOs, which provide managed care for individuals receiving Opioid Use Disorder treatment in North Carolina.

339. This grant funding was also used to reimburse OTPs and OBOT providers who provided Opioid Use Disorder treatment to individuals without private insurance or Medicaid.

[35] *VHA Programs for Veterans with Substance Use Disorders*, VHA (March 7, 2012) at 11, https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2498.

340. Payment for OTP and OBOT services must be authorized by an LME/MCO.

341. This grant funding is distinct from Medicaid, as OTP and OBOT providers did not have to be Medicaid providers to be reimbursed for Opioid Use Disorder treatment services.

342. However, providers receiving Cures Act grant funding are required to have a provider agreement/contract with an LME/MCO.

343. Upon information and belief, these provider agreements/contracts require providers to certify that they will comply with federal and state law.

344. North Carolina OTP providers receiving Cures Act grant funding must:

> [B]e licensed by the Division of Health Service Regulation, approved by the Drug Enforcement Agency, the Division of Mental Health, Developmental Disabilities and Substance Abuse Services' Drug Control Unit, the State Opioid Treatment Authority and [SAMHSA], as well as accredited by an approved accrediting body (e.g., the Joint Commission or CARF).[36]

345. "Covered services under this grant include, but are not limited to, individual, group and family therapies, intensive outpatient services, medication administration and recovery supports."[37]

346. Upon information and belief, many other states have used Cures Act funding to provide OTP and OBOT services to patients who do not have private health insurance and do not qualify for other Government Healthcare Programs.

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[36] *Opioid Treatment Under the 21st Century Cures Act: A Guide for Opioid Treatment Providers (OTPs) and Office-Based Opioid Treatment Practices (OBOTs)*, NC DHHS, https://www.ncdhhs.gov/media/1581/open.

[37] *Id.*

VI. DEFENDANTS' PARTICIPATION IN GOVERNMENT HEALTHCARE PROGRAMS

347. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

A. Defendants' Eligibility to Submit Claims to Government Healthcare Programs for Opioid Use Disorder Treatment

1. Medicare

348. In order to participate in the Medicare program and receive the bundled billing rates described below, an OTP must: (1) Be enrolled in the Medicare program; (2) have in effect a certification by SAMHSA for the OTP; (3) be accredited by an accrediting body approved by SAMHSA; and (4) have in effect a provider agreement with CMS.

349. Defendants are enrolled in the Medicare Program.

350. Defendants provide OTP services to Medicare beneficiaries at the Asheville facility and North Wilkesboro facility.

351. Upon information and belief, Defendants provide OBOT services to Medicare beneficiaries at the Asheville facility and North Wilkesboro facility.

352. Upon information and belief, Defendants provide OTP and OBOT services to Medicare beneficiaries at facilities across the United States.

353. Upon information and belief, Defendants submit bills to Medicare at the direction of Defendant Acadia in order to receive payment for OTP and OBOT services provided to Medicare beneficiaries.

354. Upon information and belief, Defendants, working in coordination with one another, applied for and received SAMHSA certifications for Defendants' North Carolina facilities, including the Asheville facility and the North Wilkesboro facility.

355. Upon information and belief, Defendants, working in coordination with one another, applied for and received accreditation by a SAMHSA-approved accrediting body—CARF International ("CARF") for Defendants' North Carolina facilities, including the Asheville facility and the North Wilkesboro facility.

356. Upon information and belief, the Asheville facility and North Wilkesboro facility both have a three-year accreditation through CARF.

357. Upon information and belief, Defendants' facilities across the United States have applied for and received SAMHSA certifications.

358. Upon information and belief, Defendants' facilities across the United States have applied for and received accreditation by SAMHSA-approved accrediting bodies.

359. Upon information and belief, Defendants have Provider Agreements with CMS to provide OBOT and OTP services to Medicare beneficiaries at Defendants' North Carolina facilities, including the Asheville facility and the North Wilkesboro facility.

360. Upon information and belief, Defendants have Provider Agreements with CMS to provide OTP and OBOT services to Medicare beneficiaries at many of their facilities across the country.

361. Upon information and belief, Defendants and their employees, agents, and contractors submit claims for OTP and OBOT services to Medicare using a Form 1500 and/or Form 1450.

362. Upon information and belief, these claims have been—and continue to be—paid by Medicare based on the implied and express certifications that Defendants make when submitting claims.

2. Medicaid

363. Upon information and belief, Defendants have provider contracts with NC DHHS

and LME/MCOs so that they may submit claims for payment to North Carolina's Medicaid Program for OBOT and OTP services.

364. Defendants provide OTP services to Medicaid beneficiaries at the Asheville facility and North Wilkesboro facility.

365. Upon information and belief, Defendants provide OBOT services to Medicaid beneficiaries at the Asheville facility and North Wilkesboro facility.

366. Upon information and belief, Defendants submit bills to North Carolina Medicaid at the direction of Defendant Acadia in order to receive payment for OBOT and OTP services provided to Medicaid beneficiaries.

367. These claims have been—and continue to be—paid by North Carolina Medicaid based on the implied and express certifications that Defendants make when submitting claims.

368. Upon information and belief, Defendants provide OBOT and OTP services to Medicaid beneficiaries in most states across the United States.

369. Upon information and belief, Defendants submit bills to these state Medicaid programs at the direction of Defendant Acadia in order to receive payment for OTP and OBOT services provided to Medicaid beneficiaries.

370. These claims have been—and continue to be—paid by state Medicaid programs based on the implied and express certifications that Defendants make when submitting claims.

371. Pursuant to CMS's OTP Medicare Billing and Payment Fact Sheet, Medicare is the primary payor for OTP services for dually eligible beneficiaries (i.e., patients who have Medicare and Medicaid coverage).

372. Upon information and belief, the claims submitted by Defendants for dually eligible

beneficiaries have been—and continue to be—paid by Medicare, as a primary payor, and Medicaid, as a secondary payor, based on the implied and express certifications that Defendants make when submitting claims.

3. TRICARE

373. Upon information and belief, Defendants have been certified by TRICARE to provide OTP and OBOT services to TRICARE beneficiaries.

374. Defendants have provided OTP services to at least one TRICARE beneficiary at the Asheville facility.

375. Upon information and belief, Defendants provide OTP and OBOT services to TRICARE beneficiaries at facilities across the State of North Carolina and the United States.

376. Defendant Acadia has a Military & Family Services ("MFS") team that "identifies appropriate treatment options for active-duty military members, veterans, and dependents who are struggling with substance use disorders and mental health concerns."[38]

377. Upon information and belief, Defendants and their employees, agents, and contractors submit claims for OTP and OBOT services to TRICARE using a Form 1500 and/or Form 1450.

378. Upon information and belief, Defendants submit bills to TRICARE at the direction of Defendant Acadia in order to receive payment for OTP and OBOT services provided to TRICARE beneficiaries.

379. These claims have been—and continue to be—paid by TRICARE based on the implied and express certifications that Defendants make when submitting claims.

[38] https://www.acadiahealthcare.com/programming-treatment/military-support/.

4. Department of Veterans Affairs

380. Upon information and belief, Defendants have contracts with the VHA and/or VA to provide OTP services to veterans.

381. The Asheville facility has had a contract with the Charles George VA Hospital to provide OTP services to veterans since approximately 2016 or 2017.

382. Upon information and belief, many of Defendants' OTP facilities in North Carolina and across the country have similar contracts with the VHA and/or VA to provide services to patients of VA hospitals and facilities that do not have an in-house OTP.

383. Upon information and belief, Defendants' Fayetteville, North Carolina facility treats a large number of VA patients due to its proximity to several large military bases.

384. Upon information and belief, Defendant Acadia's MFS team actively markets OTP services to veterans suffering from Opioid Use Disorder.

385. Upon information and belief, Defendants submit bills to the VA at the direction of Defendant Acadia in order to receive payment for OTP services provided to VA patients.

386. Upon information and belief, these OTP claims have been—and continue to be—paid by the VA based on the implied and express certifications that Defendants make when submitting claims.

5. Federal Grants – 21st Century Cures Act

387. Defendants have received, and continue to receive, payment for OTP and OBOT services through from LME/MCOs in North Carolina.

388. Many of Defendants' North Carolina facilities—including Fayetteville, Pinehurst, and the North Wilkesboro facility—have been receiving Cures Act grants for several years.

389. Upon information and belief, the Asheville facility began accepting grant funding

in mid-Summer 2021.

390. Upon information and belief, Defendants submit bills to LME/MCOs at the direction of Defendant Acadia in order to receive payment for OTP and OBOT services provided to patients who have received Cures Act grants.

391. These claims have been—and continue to be—paid by LME/MCOs based on the implied and express certifications that Defendants make when submitting claims.

392. Upon information and belief, Defendants submit bills to many other states for Cures Act grant funding at the direction of Defendant Acadia in order to receive payment for OTP and OBOT services provided to patients.

393. Upon information and belief, these claims have been—and continue to be—paid by states based on the implied and express certifications that Defendants make when submitting claims.

B. Defendants' Involvement with Government Healthcare Programs and Prior Fraud

394. Defendant Acadia has expressed concerns that these governmental programs do not generate sufficient revenue.

395. In its March 1, 2022, Form 10-K filing, the first "Financial Risk" that Acadia listed was: "Our revenue and results of operations are significantly affected by payments received from the government and third-party payors."

396. Acadia's 10-K also stated:

> Government payors in the U.S., such as Medicaid, generally reimburse us on a fee-for-service basis based on predetermined reimbursement rate schedules. As a result, we are limited in the amount we can record as revenue for our services from these government programs, and if we have a cost increase, we typically will not be able to recover this increase. In addition, the federal government and many state governments, are operating under significant budgetary pressures, and they may seek to reduce payments under their Medicaid programs for services such as those we

> provide. Government payors also tend to pay on a slower schedule. In addition to limiting the amounts they will pay for the services we provide their members, government payors may, among other things, impose prior authorization and concurrent utilization review programs that may further limit the services for which they will pay and shift patients to lower levels of care and reimbursement. Therefore, if governmental entities reduce the amounts they will pay for our services, if they elect not to continue paying for such services altogether, or if there is a significant contraction of the number of individuals covered by state Medicaid programs, our business, financial condition or results of operations could be adversely affected. In addition, if governmental entities slow their payment cycles further, our cash flow from operations could be negatively affected.[39]

397. Defendant CRC, and its predecessor, CRC Health Corp., have reached settlements with the United States, Tennessee, and West Virginia for healthcare fraud related to substance abuse and mental health treatment services.

398. On April 16, 2014, the Department of Justice announced a $9.25 million False Claims Act settlement with CRC Health Corp.[40]

399. The settlement related to "allegations that CRC knowingly submitted false claims by providing substandard treatment to adult and adolescent Medicaid patients suffering from alcohol and drug addiction at its facility in Burns, Tenn."[41]

400. The Burns, Tennessee facility was called New Life Lodge.

401. The Department of Justice Press Release states: "The government alleged that, between 2006 and 2012, New Life billed the Tennessee Medicaid program (TennCare) for substance

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[39] 10-K, *supra* note 2, at 14.

[40] *Tennessee Substance Abuse Treatment Facility Agrees to Resolve False Claims Act Allegations for $9.25 Million*, United States Department of justice (April 16, 2014), https://www.justice.gov/opa/pr/tennessee-substance-abuse-treatment-facility-agrees-resolve-false-claims-act-allegations-925.

[41] *Id.*

abuse therapy services that were not provided or were provided by therapists who were not properly licensed by the state of Tennessee."[42]

402. Upon information and belief, CRC Health Corp. is the predecessor to Defendant CRC.

403. This settlement was announced approximately six months prior to Defendant Acadia's acquisition of CRC Health Corp.

404. Upon information and belief, Defendant Acadia and Defendant CRC now own and operate the New Life Lodge.

405. In May 2019, the Department of Justice announced a $17 million healthcare fraud settlement with Defendant CRC.

406. Upon information and belief, this was the largest healthcare fraud settlement in the history of West Virginia ("the 2019 Settlement").

407. According to a Department of Justice Press Release, the 2019 Settlement addressed the following conduct:

> From January 1, 2012 to July 31, 2018, Acadia's treatment centers sent urine and blood samples to an outside laboratory, San Diego Reference Laboratory (the "San Diego Lab") for all moderate and high complexity drug testing. The San Diego Lab performed the testing and invoiced Acadia's treatment centers for the services, and did so at the request of the treatment centers. Acadia's treatment centers paid the San Diego Lab directly. However, Acadia's West Virginia treatment centers then billed West Virginia Medicaid for the urine and blood testing performed by the San Diego Lab, as though the testing had been performed by the treatment centers. In the claims for reimbursement submitted to Medicaid, Acadia's treatment centers represented that they had performed the moderate and/or high complexity laboratory services. Medicaid, induced by the claims submitted by Acadia's treatment centers, paid the treatment centers a substantially higher amount than the San Diego Lab charged to actually perform the testing. Medicaid regulations and policies specifically prohibited Acadia's treatment centers from seeking reimbursement for moderate and complex urine and blood testing which they were not certified to perform, and did not, in fact, perform.

[42] *Id.*

> Medicaid paid Acadia's treatment centers $8,500,000 as a result of these moderate and complex urine and blood testing claims, resulting in a loss of $2,181,100 to the State of West Virginia and $6,318,900 to the United States. . . . As a result of the $17 million settlement, which represents twice the actual loss suffered by Medicaid, both the state and federal programs will be made whole.[43]

408. As part of the 2019 Settlement, Defendant Acadia and its subsidiary, Defendant CRC, entered into a five-year Corporate Integrity Agreement ("CIA") with HHS-OIG.[44]

409. The CIA "applies to CRC Health, LLC and to Acadia in its oversight, operation, and management of CRC Health, LLC."[45]

410. The CIA requires Defendant Acadia to establish and maintain an extensive Compliance Program.

411. Within 90 days after the Effective Date[46] of the CIA, Defendant Acadia was required to appoint a Compliance Officer.

412. The Compliance Office is responsible for, "without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in th[e] CIA and with Federal health care program requirements;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Acadia (Acadia Board) and shall be authorized to report on such matters to the Acadia Board at any time. Written documentation of the

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[43] *United States Attorney Announces $17 Million Healthcare Fraud Settlement*, United States Attorney's Office for the Southern District of West Virginia (May 6, 2019), https://www. justice.gov/usao-sdwv/pr/united-states-attorney-announces-17-million-healthcare-fraud-settleme nt.

[44] Corporate Integrity Agreement, https://oig.hhs.gov/fraud/cia/agreements/CRC_Heatlh_LLC_and_Acadia_Healthcare_Company_Inc_05032019.pdf [hereinafter "CIA"].

[45] *Id.* at 1. Defendant Acadia and Defendant CRC are collectively referred to as "CRC" in the CIA.

[46] The Effective Date is the "date on which the final signatory of th[e] CIA executes th[e] CIA." *Id.* The final signatory signed the CIA on May 3, 2019. *Id.* at 31. Accordingly, and upon information and belief, the Effective Date of the CIA is May 3, 2019.

Compliance Officer's reports to the Board shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by CRC as well as any reporting obligations created under th[e] CIA."[47]

413. The CIA required Defendant Acadia to appoint a Compliance Committee within 90 days after the Effective Date of the CIA.

414. The CIA also required Defendant Acadia to appoint a Board of Directors Compliance Committee ("Board Committee").

415. The Board Committee is required to meet at least quarterly "to review and oversee CRC's compliance program . . . ."[48]

416. Additionally, the Board Committee is responsible for adopting an annual resolution, "signed by each member of the Board summarizing its review and oversight of CRC's compliance with Federal health care program requirements and the obligations of th[e] CIA."[49]

417. At a minimum, Defendant Acadia's Board resolution is required to include the following language:

> "The Board Committee has made a reasonable inquiry into the operations of CRC's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board Committee has concluded that, to the best of its knowledge, CRC has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."[50]

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[47] *Id.* at 1–2.

[48] *Id.* at 4.

[49] *Id.*

[50] *Id.*

418. The CIA also required certain employees of Defendant Acadia and Defendant CRC "to monitor and oversee activities within their areas of authority and . . . annually certify that the applicable CRC department is in compliance with applicable Federal health care program requirements and the obligations of th[e] CIA."[51]

419. At a minimum, "[t]hese Certifying Employees shall include . . . the following: Division CEO/President, Division CFO, Senior Vice President, Regional Vice Presidents, and Division Compliance Officer."[52]

420. These Certifying Employees are required to sign a certification every annual reporting period that states:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and CRC policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of CRC is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."[53]

421. The CIA also required Defendant Acadia and Defendant CRC to "develop and implement written policies and procedures regarding the operation of its compliance program . . . and CRC's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of th[e] CIA, CRC shall enforce its Policies and Procedures and shall make

[51] *Id.* at 5.

[52] *Id.*

[53] *Id.*

compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons."[54]

422. The CIA defines "Covered Persons" to include, *inter alia*, (a) "all contractors, subcontractors, agents, and other persons who furnished patient care items or services or who perform billing or coding functions on behalf of CRC, excluding vendors whose sole connection with CRC is selling or otherwise providing medical supplies or equipment to CRC" and (b) "all physicians and other non-physician practitioners who are members of CRC's active medical staff."[55]

423. Defendant ATS and its employees, agents, contractors, and subcontractors are "Covered Persons" under the terms of the CIA.

424. The CIA imposes training and education requirements for these "Covered Persons":

> Within 90 days after the Effective Date, CRC shall develop a written plan (Training Plan) that outlines the steps CRC will take to ensure that all Covered Persons receive at least annual training regarding CRC's CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. CRC shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.[56]

425. Defendant Acadia and Defendant CRC must "make available to OIG, upon request, training materials and records verifying that Covered Persons and Acadia Board members have timely received the training required under this section."[57]

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[54] *Id.* at 6.

[55] *Id.* at 1–2.

[56] *Id.* at 6.

[57] *Id.* at 7.

426. Additionally, the CIA required Defendant Acadia and Defendant CRC to "develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with CRC's participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries."[58]

427. This risk assessment and internal review process requires Defendant Acadia and Defendant CRC to, at least annually: "(1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans."[59]

428. The CIA also required Defendant Acadia and Defendant CRC to develop a Disclosure Program within 90 days after the Effective Date.

429. The Disclosure Program must include "a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with CRC's policies, conduct, practices or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law."[60]

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[58] *Id.* at 8.

[59] *Id.*

[60] *Id.*

430. Defendant Acadia and Defendant CRC must "appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas)."[61]

431. "The Disclosure Program also shall include a requirement that all of CRC's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by CRC."[62]

432. Upon receipt of a disclosure, the Compliance Officer or his or her designee must gather information from the individual making the disclosure and "make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted."[63]

433. The CIA also contains the following requirement: "For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, CRC shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted."[64]

434. The CIA requires the Compliance Officer or his or her designee to log every disclosure within two business days of receipt.

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[61] *Id.* at 8–9.

[62] *Id.* at 9.

[63] *Id.*

[64] *Id.*

435. If Defendant Acadia or Defendant CRC determine "(after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event," the CIA requires them to notify HHS-OIG in writing within 30 days.[65]

436. The CIA defines a "Reportable Event" as: (a) a substantial overpayment; (b) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; (c) the employment of or contracting with a Covered Person who is an Ineligible Person as defined by [the CIA]; or (d) the filing of a bankruptcy petition by Defendant CRC.[66]

437. When Defendant Acadia and Defendant CRC learn of a Reportable Event, they must report the event to HHS-OIG.

438. The report must include: (a) a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event; (b) a statement of the Federal criminal, civil, or administrative laws that are probably violated by the Reportable Event, if any; (c) the Federal healthcare programs affected by the Reportable Event; (d) a description of the steps taken by Defendant Acadia and Defendant CRC to identify and quantify any overpayments; and (e) a description of Defendant Acadia and Defendant CRC's actions taken to correct the Reportable Event and prevent it from recurring.[67]

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[65] *Id.* at 12.

[66] *Id.*

[67] *Id.* at 13.

439. Defendant Acadia and Defendant CRC must also submit a written report to HHS-OIG during each of the five years covered by the CIA. These annual reports must include, *inter alia*, a summary of all Reportable Events during the applicable year. Importantly, the annual report must also contain a certification by the Compliance Officer and Chief Executive Officer that: (a) to the best of his or her knowledge, except as otherwise described in the report, Defendant Acadia and Defendant CRC have implemented and is in compliance with all of the requirements of the CIA; (b) he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and (c) he or she understands that the certification is being provided to and relied upon by the United States.[68]

440. Furthermore, the CIA permits HHS-OIG to "conduct interviews, examine and/or request copies of or copy CRC's books, records, and other documents and supporting materials, and conduct on-site reviews of any of CRC's locations, for the purpose of verifying and evaluating:" (a) Defendant Acadia and Defendant CRC's compliance with the CIA and (b) Defendant Acadia and Defendant CRC's compliance with the requirements of Federal healthcare programs.[69]

441. The CIA also provides for contractual remedies—including a range of stipulated monetary penalties—if Defendant Acadia and/or Defendant CRC breaches the terms of the CIA. These remedies are in addition to other damages and penalties available under Federal and State law.

[68] *Id.* at 18–19.

[69] *Id.* at 21.

442. Moreover, Defendant Acadia and Defendant CRC "agree[d] that a material breach of th[e] CIA by CRC constitutes an independent basis for CRC's exclusion from participation in the Federal health care programs."[70]

443. The CIA defines a "material breach" to include, *inter alia*, "a failure by CRC to report a Reportable Event, take correction action, or make the appropriate refunds," as required by the CIA.[71]

444. The CIA also defines a "material breach to include, *inter alia*, "repeated violations or a flagrant violation of any of the obligations under th[e] CIA . . . ."[72]

445. The CIA states: "All requirements and remedies set forth in th[e] CIA are in addition to and do not affect (1) CRC's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements."[73]

446. In its March 1, 2022, 10-K, Defendant Acadia emphasized the severe consequences of noncompliance with the requirements of the CIA:

> Material, uncorrected violations of the CIA could lead to our suspension or exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs and repayment obligations. In addition, we are subject to possible civil penalties for failure to substantially comply with the terms of the CIA, including stipulated penalties ranging between $1,000 to $2,500 per day. We are also subject to a stipulated penalty of $50,000 for each false certification made by us or on our behalf, pursuant to the reporting provisions of the CIA. The CIA increases the amount of information we must provide to the federal government regarding our healthcare practices and our compliance with federal regulations. The reports we

[70] *Id*. at 25–26 (emphasis added).

[71] *Id.* at 25.

[72] *Id.*

[73] *Id.* at 29.

> provide in connection with the CIA could result in greater scrutiny by regulatory authorities.[74]

447. The 10-K and CIA demonstrate that Defendant Acadia and Defendant CRC are aware of their obligations under State and Federal law.

448. Upon information and belief, Defendant Acadia created a Healthcare Code of Conduct ("Code of Conduct") as a result of the CIA.[75]

449. The Code of Conduct states that Defendant Acadia has a Compliance Program in place:

> An important part of the Compliance Program is to ensure that we have processes in place to help prevent, detect, and deter fraud, waste, and abuse in government healthcare programs. Important elements of the program include:
>
> + Written policies and procedures,
> + Code of Conduct,
> + Corporate Compliance Officer and compliance committees,
> + Training and education,
> + Screening employees and vendors for government sanctions,
> + Auditing and monitoring of core risk areas, and
> + Providing a Confidential Disclosure Program (Hotline) for confidentially reporting concerns.[76]

450. The Code of Conduct states:

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[74] 10-K, *supra* note 2, at 29.

[75] https://www.keystonetreatment.com/wp-content/uploads/2022/02/Acadia-Compliance-Booklet-CodeofConduct.pdf.

[76] *Id.* at 5.

> Acadia's mission is to create a world-class organization that sets the standard for excellence in the treatment of specialty behavioral health and addiction disorders.
>
> In fulfilling this mission, Acadia is dedicated to adhering to the highest ethical standards and recognizes the importance of full compliance with all applicable federal and state laws, rules, and regulations.
>
> The Compliance Program helps guide Acadia in its management and operation of compliance-related activities and provides guidance to employees on how to perform job responsibilities ethically and legally.[77]

451. The Code of Conduct emphasizes the importance of complying with "federal, state, and local laws, rules, and regulations" and being honest with accrediting bodies and government officials.[78]

452. The Code of Conduct states:

> Healthcare services may be provided only pursuant to federal, state, and local laws, rules, and regulations. As a result, we are visited by various accrediting, auditing, and investigating bodies. We should always demonstrate our culture of integrity by treating accrediting agencies and bodies in a forthright manner. We should not mislead a surveyor or survey team.[79]

453. The Code of Conduct also describes federal and state False Claims Act laws.

454. In this section of the Code of Conduct, Defendant Acadia provides the following example of potential fraud and how employees should respond:

> **SITUATION:**
>
> A member of your department is concerned that counseling sessions are not being charged or billed accurately.
>
> **SOLUTION:**

---

[77] *Id.* at 4.

[78] *Id.* at 19.

[79] *Id.*

> We want to make sure that individuals know that they have many options to find answers to their questions, including a member of management, the Facility Compliance Leader, or the Hotline.[80]

455. The Code of Conduct also states that:

> Coding of diagnoses and procedures will be in accordance with the Centers for Medicare and Medicaid Services (CMS) recognized coding guidelines. The organization will maintain a routine auditing and monitoring program to verify the accuracy and validity of coded data and claims regardless of the source of payment.
>
> All individuals responsible for coding and billing for services will adhere to all official coding and billing guidelines, rules, regulations, statutes, and laws. You are prohibited from knowingly causing or permitting false or fraudulent claims.[81]

456. The Code of Conduct states that employees must "take the Code of Conduct course in [the] Learning Management System (LMS)" and acknowledge their obligations under the Code of Conduct on an annual basis.[82]

457. Under the terms of the CIA, Defendants have a contractual obligation to train their employees, agents, contractors, and subcontractors about the above requirements.

458. As detailed more fully below, Defendants and their employees, agents, contractors, and subcontractors failed to comply with the terms of the CIA when Relator repeatedly alerted them to the fraudulent conduct detailed below.

VII. DEFENDANTS' FRAUDULENT SCHEME

459. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

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[80] *Id.* at 20.

[81] *Id.* at 23.

[82] *Id.* at 24, 28.

A. Opioid Use Disorder Services Provided by Defendants

460. At the clinics owned and operated by Defendants, patients are treated with Methadone, Buprenorphine, or Naltrexone as part of an OTP or through OBOT.

461. The Asheville facility is an OTP and also provides OBOT services.

462. The Asheville facility treats patients with Methadone or Buprenorphine, but does not prescribe Naltrexone.

463. Many of the Asheville facility's patients are beneficiaries of Government Healthcare Programs, including Medicare, Medicaid, TRICARE, VA, and Cures Act Grants.

464. At the Asheville facility, Relator's job as Assistant Medical Director was to handle physical assessments of patients and prescribe appropriate doses of Methadone and Buprenorphine.

465. The Asheville facility has counselors and therapists to provide behavioral health services to OTP and OBOT patients.

466. MAT patients at Defendants' clinics—including the Asheville facility—are supposed to receive both medication and behavioral health treatment, which includes group and/or individual counseling.

467. Therapy and/or counseling are integral parts of every patient's treatment plan.

468. Patients' treatment plans indicate the frequency and type of counseling services that must be provided.

469. At Defendants' clinics, OTP patients must physically come into the clinic for their medications and/or prescriptions.

470. Because of the COVID-19 pandemic, patients at the Asheville facility and, upon information and belief, Defendants' other OTP facilities can receive their counseling appointments by video or, if video is unavailable, by telephone.

471. When patients come into Defendants' facilities for their medication, they go to a "dosing window" and a nurse hands them their medication.

472. Patients who come to the Asheville facility to pick up their medication typically only spend ten to fifteen minutes at the clinic.

473. Upon information and belief, OTP patients at Defendants' other facilities spend a similar amount of time at the facility to receive their medication.

474. OTP patients spend a longer amount of time at Defendants' facilities if they have a medical or counseling/therapy appointment.

475. How often patients come into the Asheville facility for medication treatment depends on the patient and her treatment plan.

476. For example, at Defendants' facilities, how often patients come into the clinics for their medication depends on what "level" the patient is.

477. Generally, patients come into the clinic six days per week to get their medication.

478. Other patients have "earned" some take-home medication and need to come into the clinic two to three times per week to get their medication.[83] "Level 5" patients come to the OTP once per week to get medication, "Level 6" patients come to the OTP once every fourteen days for medication, and "Level 7" patients come to the OTP once every twenty-eight days for medication.

[83] The reason that take-home medication is "earned" is because the medication that is used to treat Opioid Use Disorders carry a risk of abuse themselves.

479. How often patients receive counseling or therapy at the Asheville facility and, upon information and belief, Defendants' other facilities depends on whether the patient is new or established.

480. Upon information and belief, established patients are supposed to receive counseling at least once per month at Defendants' clinics.

481. Upon information and belief, new patients are supposed to be seen at least twice a month for counseling with clinic-contact at least every week.

482. Upon information and belief, after 90 days, the patient would change to counseling at least once per month.

B. Defendants' Fraudulent Conduct and Falsification of Patient Records

1. September 2020: Defendants Create False Group Therapy Notes

483. Beginning in September 2020, Relator began noticing fraudulent activity occurring at Defendants' Asheville facility.

484. The Asheville facility was documenting that they were doing group therapy, but they were not actually doing group therapy.

485. Relator asked her patients if they were receiving group therapy, and they told her that the Asheville facility was not providing group therapy.

486. Upon information and belief, the Asheville facility has not held any group therapy sessions for more than two years.

487. Relator learned that therapists and counselors were signing group therapy treatment notes that stated that they facilitated "impromptu lobby group," "continuous lobby group," "sidewalk group," and—later—"telehealth group" therapy sessions and "bibliotherapy."

488. These group therapy notes stated that therapists held group therapy sessions in the lobby of the Asheville facility, on the sidewalk outside of the Asheville facility, or by telephone in light of the COVID-19 pandemic.

489. But these group therapy sessions never happened.

490. During this time period, Relator never saw a therapist or counselor conduct a group therapy session in any setting, much less in the lobby of the Asheville facility or on the sidewalk outside the Asheville facility.

491. Upon information and belief, the Asheville facility did not have technology capable of facilitating a telephone group therapy session.

492. The Clinic Director of the Asheville facility, Jason Hines, had a conference call line for meetings, but it was not used for patient visits, counseling, or therapy.

493. The fraudulent group therapy notes often contained significant detail, including a description of dialogue between participants.

494. Counselors and/or therapists reused the same fraudulent group therapy notes for different patients.

495. Sometimes, different counselors and/or therapists reused the same fraudulent group therapy notes for the same patients on different dates.

496. For example, Patient 1's medical records state that she participated in an "impromptu lobby group" on September 2, 2020 on the subject of "Relapse is Not a Sign of Failure."

497. This group therapy note concludes with a description of the purported responses from and interaction between group therapy members:

> Group members were asked what they thought the analogy about the flooded house meant. The overall majority of the clients were able to find the meaning. One client wrote, "…just deciding to get clean doesn't fix the damage to your body and brain."

> Another wrote, "quitting illicit drugs doesn't solve your problems, but it stops it from becoming worse."
>
> Clients were then asked if they felt like they had, at this point, completely "turned off the faucet" at this time. Answered (sic) varied in regards to their current recovery effort. Those who answered, "yes" were asked about the damages they've repaired. Client's discussed their accomplishments in "people, places and things", "family relationships", "self-esteem", and "overcoming the stigma attached to being an addict "," continued illicit free urinalysis screens", and "removing the numbers from the telephone and staying clear of old hangouts", etc.
> Assessment: All clients were given the opportunity to list some of the items they had not yet repaired. Group members discussed the need to continue to repair relationships, stop using drugs as a crutch when emotions such as anger or fear take over, repair overall health, begin to care for one's self, working on mental health, working on one's own attitude, repairing financial status and credit, etc.
>
> Plan: Group members were thanked for their work and feedback in this exercise. Group facilitator encouraged client to keep transforming their life and make the necessary repairs in life.

498. The Clinic Director of the Asheville facility, Jason Hines, signed this group therapy note on September 3, 2020 at 4:11:10 PM.

499. This group therapy session did not occur.

500. Other therapists and counselors at the Asheville facility reused this group therapy note for other patients.

501. On March 3, 2021, Counselor Ernest Davis signed a "sidewalk group" therapy note for Patient 2 that concluded with:

> Group members were asked what they thought the analogy about the flooded house meant. The overall majority of the clients were able to find the meaning. One client wrote, "…just deciding to get clean doesn't fix the damage to your body and brain." Another wrote, "quitting illicit drugs doesn't solve your problems, but it stops it from becoming worse."
>
> Clients were then asked if they felt like they had, at this point, completely "turned off the faucet" at this time. Answered varied in regards to their current recovery effort. Those who answered, "yes" were asked about the damages they've repaired. Client's discussed their accomplishments in "people, places and things", "family relationships", "self-esteem", and "overcoming the stigma attached to being an addict "," continued illicit free urinalysis screens", and "removing the numbers from

> the telephone and staying clear of old hangouts", etc. All clients were given the opportunity to list some of the items they had not yet repaired. Group members discussed the need to continue to repair relationships, stop using drugs as a crutch when emotions such as anger or fear take over, repair overall health, begin to care for one's self, working on mental health, working on one's own attitude, repairing financial status and credit, etc. Group members were thanked for their work and feedback in this exercise. Group facilitator encouraged client to keep transforming their life and make the necessary repairs in life.

502. The only difference between this language and the language in Patient 1's note from approximately six months earlier is the omission of the words "Assessment:" and "Plan:".

503. Counselor Anita Bacon signed an identical fraudulent "sidewalk group" therapy note for Patient 1 on March 4, 2021.

504. Counselor Anita Bacon signed an identical fraudulent "sidewalk group" therapy note for Patient 3 on March 4, 2021.

505. Counselor Anita Bacon signed an identical fraudulent "sidewalk group" therapy note for Patient 4 on March 5, 2021.

506. None of the group therapy sessions listed above actually occurred.

507. Relator discovered other fraudulent group therapy notes on different topics that were duplicated and used by different counselors and therapists.

508. Upon information and belief, Defendants provided the Asheville facility's counselors and therapists with prewritten, group therapy notes to use for patients.

509. The Asheville facility's staff then copied and pasted the template group therapy note into individual group therapy notes for patients who picked up medications or had assessments that week.

510. The counselors and therapists at the Asheville facility were systematically duplicating fraudulent group therapy notes to give the illusion that they were providing group therapy.

511. Upon information and belief, Defendants engage in this fraudulent conduct to save time and money so that they can see more Government Healthcare Program patients without taking the necessary time to provide counseling services.

512. Upon information and belief, and as detailed below, this policy was directed by Defendants at the corporate level.

513. Upon information and belief, Defendants submitted bills to commercial insurance companies and Government Healthcare Programs for these false and fraudulent group therapy sessions.

2. March 2021: Defendants' Fraud Escalates—"Bibliotherapy"

514. In approximately March 2021, Relator observed patients at the Asheville facility filling out worksheets during their appointments.

515. Relator learned that the Asheville facility was using these worksheets in order to falsely document that its counselors and therapists were performing a certain type of group therapy called "bibliotherapy."

516. Bibliotherapy is form of therapy[84] where the therapist provides the patient with a book or article to read and then the patient comes back into the clinic to discuss what was read with the counselor.

517. Bibliotherapy can be done individually or as a group.

[84] While there is some evidence to support the use of bibliotherapy in opioid treatment programs, it is far from overwhelming. For example, the National Institute on Drug Abuse Research Abstract Database contains limited references to scientific studies involving bibliotherapy. The only available abstract discussed a study involving ten inmates in a Malaysian government-aided rehabilitation session. The study only examined six group counseling sessions with these ten individuals. Adb Hussin, *Reading to Recover: Exploring Bibliotherapy as a Motivational Tool for Recovering Addicts*, National Institute on Drug Abuse, https://www.drugabuse.gov/ international/abstracts/reading-to-recover-exploring-bibliotherapy-motivational-tool-recovering-addicts.

518. But bibliotherapy can only be effective when there is interaction between patients, their peers, and/or therapists.

519. At the Asheville facility, when a patient checked in at reception, an employee gave the patient a worksheet to fill out during his or her visit.

520. These worksheets contained information and questions about various topics, including loneliness, forgiveness, and gas-lighting.

521. Many of the worksheet had titles that were identical to the topics of the false group therapy notes Defendants had been using since at least September 2020.

522. The worksheets typically contained pre-written text on the topics with clip-art pictures and blank lines for patients to respond to questions.

523. An employee of the Asheville facility collected the worksheets from patients before they left the building.

524. Upon information and belief, the Asheville facility added these worksheets to the patient's file and medical records.

525. The Asheville facility's counselors and therapists did not discuss the worksheets or responses with patients.

526. The Asheville facility's counselors and therapists then created group therapy notes that purported to combine the worksheet responses of numerous patients.

527. However, the bibliotherapy group therapy notes were actually false and based on templates provided by Defendants and prior false group therapy notes.

528. For example, Defendants distributed a worksheet titled, "Relapse is Not a Sign of Failure" to patients.

529. On July 6, 2021, Counselor Kathy Wunder signed a fraudulent group therapy note for Patient 5 on this topic, which concluded with the following language:

> Group members were asked what they thought the analogy about the flooded house meant. The overall majority of the clients were able to find the meaning. One client wrote, "…just deciding to get clean doesn't fix the damage to your body and brain." Another wrote, "quitting illicit drugs doesn't solve your problems, but it stops it from becoming worse."
>
> Clients were then asked if they felt like they had, at this point, completely "turned off the faucet" at this time. Answered varied in regards to their current recovery effort. Those who answered, "yes" were asked about the damages they've repaired. Client's discussed their accomplishments in "people, places and things", "family relationships", "self-esteem", and "overcoming the stigma attached to being an addict "," continued illicit free urinalysis screens", and "removing the numbers from the telephone and staying clear of old hangouts", etc. All clients were given the opportunity to list some of the items they had not yet repaired. Group members discussed the need to continue to repair relationships, stop using drugs as a crutch when emotions such as anger or fear take over, repair overall health, begin to care for one's self, working on mental health, working on one's own attitude, repairing financial status and credit, etc.

530. This language is identical to the language previously used in the following false group therapy notes:

a. An "impromptu lobby group" note for Patient 1 signed by Clinic Director and Counselor Jason Hines on September 3, 2020. Patient 1's note contained the word "Assessment:" before the sentence, "All clients were given the opportunity to list some of the items they had not yet repaired." The remainder of the quoted language is identical.

b. A "sidewalk group" therapy note for Patient 2 signed by Counselor Ernest Davis on March 3, 2021.

c. A "sidewalk group" therapy note for Patient 1 signed by Counselor Anita Bacon on March 3, 2021.

d. A "sidewalk group" therapy note for Patient 3 signed by Counselor Anita Bacon on March 4, 2021.

e. A "sidewalk group" therapy note for Patient 4 signed by Counselor Anita Bacon on March 5, 2021.

531. Upon information and belief, Defendants provided the Asheville facility's counselors and therapists with prewritten, bibliotherapy group therapy notes to use for patients.

532. Starting no later than June 2021, Defendants began sending out emails with templates to make the creation of fraudulent bibliotherapy group therapy notes easier.

533. Each week, Matthew Lawson—the Asheville facility's Clinical Manager—sent an email to the facility staff with a template bibliotherapy group therapy note that was to be used that week.

534. The Asheville facility's counselors and therapists then copied and pasted the template group therapy note into individual group therapy notes for patients who picked up medications or had assessments that week.

535. These false notes were then signed—often electronically—by counselors or therapists.

536. These template bibliotherapy notes were sometimes obviously copied from prior group therapy notes.

537. For example, on June 21, 2021, Matthew Lawson sent an email to the Asheville facility's employees with the "Bibliotherapy note for week 06/21/2021."

538. The note began: "Counselor facilitated a *continuous lobby group* today while observing the CDC guidelines on social distancing and use of protective masks." (emphasis added).

539. Other bibliotherapy notes are facially inconsistent because they blend various forms of false group therapy sessions.

540. For example, on July 12, 2021, Matthew Lawson signed a "Telehealth Group (COVID)" note for Patient 13, which states: "**Telehealth Group (COVID)** – The following is a worksheet provided to patients as part of a CBT approach utilizing **bibliotherapy**. . . . Group

Leader facilitated a **sidewalk group** while observing the CDC's guidelines on social distancing and use of facemasks. Group Leader facilitated group session by engaging members in activity on 'Relapse is Not a Sign of Failure'." (emphasis added).

541. Thus, this note simultaneously purported to represent a simultaneous: (1) a tele-health group therapy session; (2) a sidewalk group therapy session; and (3) a counselor or therapist compiling worksheets into a bibliotherapy group therapy note.

542. None of these group therapy sessions happened, and this false bibliotherapy group therapy note was a truncated version of an often reused group therapy note titled, "Relapse is Not a Sign of Failure."

543. Upon information and belief, Defendants engage in this fraudulent conduct to save time and money so that they can see more Government Healthcare Program patients without taking the necessary time to provide counseling services.

544. In an attempt to conceal the fraudulent nature of these group therapy notes, the weekly emails discussed above often contained a disclaimer that this bibliotherapy was not intended to replace actual individual or group therapy.

545. For example, on July 19, 2021, Matt Lawson—the Asheville facility's Clinical Manager—sent an email to the Asheville facility's employees that contained the following introductory paragraph:

> The following is a worksheet provided to patients as part of a CBT approach utilizing bibliotherapy. The intent is to allow patients the opportunity to contemplate topics that may otherwise go unexplored in general counseling sessions. Each worksheet will be reviewed by the patient's counselor and aggregated into an individualized group note. This is intended as a tool to improve the therapeutic alliance by giving the patient time to contemplate and compose their response in a more intentional and less reactive way. In many cases the responses may be more transparent and display more vulnerability than under usual circumstances involving active observation. It is in this way the therapeutic alliance can be enriched while reducing the amount of time in which the patient needs to commit to in clinic visits.

> This is not meant to be a replacement for face-to-face or group sessions, but rather augment and inform those approaches while being conscientious of the risks that abound due to the COVID-19 Pandemic. It is recommended that each patient devote 45 minutes to the assignment.

546. Upon information and belief, the purpose of these facility-wide emails with pre-populated group therapy notes was to avoid providing actual therapy to patients and to increase Defendants' revenue.

547. Despite Defendants' statement in the above email that the bibliotherapy worksheets were not meant to be a "replacement for face-to-face or group sessions," the Asheville facility was not conducting group therapy or adequate individual therapy.

548. Upon information and belief, and as detailed below, this policy was directed by Defendants at the corporate level.

549. Upon information and belief, Defendants submitted bills to commercial insurance companies or Government Healthcare Programs for this false and fraudulent bibliotherapy.

3. Defendants Falsification of Group Therapy Notes is Exacerbated by its Failure to Provide Legally Adequate Individual Therapy

550. Upon information and belief, Defendants do not perform the required amount of individual therapy and counseling sessions required under patients' treatment plans and federal and state law.

551. During the COVID-19 pandemic, the Asheville facility began conducting non-contact individual therapy and/or counseling sessions.

552. Defendants made no attempt to ascertain whether patients had the ability to attend therapy and/or counseling sessions in person or by video.

553. Instead, Defendants directed their employees in the Asheville facility to perform therapy and/or counseling solely by telephone.

554. Thus, counselors and therapists at the Asheville facility often called patients, had a brief phone call with them, and documented the session as a full individual therapy session.

555. Frequently, no actual therapy and/or counseling occurred during the call.

556. Patients at the Asheville facility are not receiving any meaningful therapy from Defendants.

557. Instead, upon information and belief, Defendants provide inadequate individual therapy, no group therapy, and bill Government Healthcare Programs as if an entire suite of services are provided to its patients.

558. Federal and State law mandate therapy and counseling for a reason: It is necessary to ensure that patients with Opioid Use Disorder receive mental health treatment and do not relapse.

559. While medication helps treat the physical cravings and withdrawal associated with opioid addiction, therapy and counseling are the only means to treat underlying trauma and unearth and treat the underlying reasons for addiction.

C. Defendants' Fraudulent Conduct is Widespread and Directed by Corporate

560. Upon information and belief, the fraudulent conduct at the Asheville facility detailed above occurred at many of Defendants' facilities.

561. Upon information and belief, Defendants knew about and directed the creation of fraudulent group therapy notes and the provision of inadequate individual therapy.

562. Upon information and belief, Defendants have engaged in—and continue to engage in—a pattern and practice of creating fraudulent group therapy notes and providing inadequate individual therapy.

563. On July 6, 2021, Matt Lawson sent an email to the Asheville facility's employees with a false bibliotherapy group therapy note for counselors and therapists to use for the week.

564. A short time later, Matt Lawson sent a follow-up email telling the Asheville facility's employees to disregard the prior email and use a different, shorter false group therapy note.

565. The stated reason for this change was that: "Corporate wants less detail."

566. Upon information and belief, the Asheville facility's method of falsifying group therapy records is a corporate policy that has been implemented in facilities owned and operated by Defendants across the country.

567. Additionally, upon information and belief, this email indicates that Defendants actively monitor the level of detail in the fraudulent group therapy notes.

568. Upon information and belief, including less detail in a false group therapy note saves time and money and allows Defendants to see more beneficiaries of Government Healthcare Programs.

569. Upon information and belief, this fraudulent conduct is still occurring at Defendants' facilities.

570. Relator has firsthand knowledge about how this fraudulent scheme operates in the Asheville facility.

571. But the fraud is not limited to the Asheville facility.

572. The Medical Director of the North Wilkesboro facility told Relator that group therapy notes are also falsified at the North Wilkesboro facility and that she notified the Clinic Director about the fraud.

573. Relator also reported the fraud to the Asheville facility's management several times.

574. In March 2021, Relator told the Clinic Director of the Asheville facility, Jason Hines, that Defendants were creating fraudulent group therapy notes.

575. Mr. Hines told Relator that this conduct was occurring at other North Carolina locations, including Defendants' Pinehurst and Fayetteville locations.

576. Mr. Hines also told Relator that Jessica Tighe—Defendants' Regional Director—stated that Relator should "stay in her lane."

577. Upon information and belief, Jessica Tighe oversees Defendants' activities within North Carolina and is supervised by Erin McCarthy—Defendants' Regional Vice President.

578. Relator informed Mr. Hines again in May 2021 and July 2021 that the fraudulent group therapy notes were still being created and used.

579. Upon information and belief, neither Mr. Hines, Ms. Tighe, or Ms. McCarthy took any corrective action to stop the fraud.

580. Upon information and belief, Mr. Hines' response, Ms. Tighe's warning to Relator, and the email, discussed above, with the corporate directive to provide less detail in the fraudulent group therapy notes indicates that this fraud is widespread across Defendants' facilities.

581. Upon information and belief, the conduct is occurring at Defendants' facilities across the State of North Carolina and across the United States, including but not limited to the following states: Alaska, Arizona, Arkansas, California, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

D. Example of Defendants' False Claims to Government Healthcare Programs

582. Patient 6 receives Methadone from the Asheville facility's OTP.

583. Patient 6 began treatment at the Asheville facility on April 10, 2020.

584. Patient 6 is a Medicare and Medicaid beneficiary.

585. Patient 6's initial treatment plan stated that he "will participate in all program counseling requirements."

586. During intake, Patient 6 expressed a desire to reestablish care for his mental health diagnoses.

587. The initial treatment plan states: "Staff will provide approrpiate (sic) referrals to mental health providers and maintain accountability to ensure that patient follows through with initial and follow-up appointments. Counselor will establish and maintain coordination of care to ensure ongoing communicatoin (sic) between providers."

588. Despite the initial treatment plan's requirement that Patient 6 participate in all counseling requirements, Defendants never provided the option to participate in group therapy.

589. Patient 6 came to the Asheville, North Carolina clinic on May 19, 2021 to see Relator for an appointment for a physical assessment and for Relator to assess and review his current medications.

590. Patient 6 told Relator that he is asked to fill out a bibliotherapy worksheet almost every time he comes into the clinic.

591. Patient 6 did not participate in any group therapy when he went to the Asheville facility on May 19, 2021.

592. Patient 6 told Relator that he has never participated in any group therapy at Defendants' facilities.

593. However, Patient 6's chart contains numerous group therapy notes, indicating that he participated in group therapy many times.

594. Patient 6's chart contains detailed group therapy notes for several visits in April 2021.

595. For example, Patient 6's chart contains a group therapy note from April 7, 2021 that is signed by Counselor Shawn Landreth.

596. The note states that Landreth "facilitated a continuous lobby group" on the topic of "What prevents me from being in the moment?"

597. The note purports to contain a description of interactions between Landreth and group members.

598. The yellow highlighted portion of the note purports to state group member's responses and the green highlighted portion contains the counselor's assessment:

Case Notes

Date: 5/19/2021
Time: 13:23:32

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Group Note - Data: Group Leader facilitated a continuous lobby group while observing the CDC's guidelines on social distancing and use of facemasks. Counselor engaged clients in a group session on a topic of "What prevents me from being in the moment?" Counselor explained to members the question is so important to answer because any effort you make to find greater happiness or grow as a person will be relatively useless if too many things take you away from appreciating the present moment. Counselor explained that one can't remain present all of the time, but should try to when it counts.
Counselor explained if the answer is "my phone or social media", then it was recommend to develop a habit of turning off your phone in 30-minute increments or making airplane mode their best friend. Counselor discussed creating tiny phone-less moments. Counselor discussed if work or relationship obligations prevented them from distancing themselves from their phones, they were told try keeping your phone on ringer and leaving it in another room. Some of the clients in the group discussed the fact they were doing these things and others discussed trying to in the coming week. One client on the line stated he goes for walks and leaves his phone at home just "to get away from the noise".
It was discussed that evolving the ability to distance yourself from your phone is working on just about the same mental muscle as distancing yourself from bad thoughts. If you can't separate from your phone, think about the following fact: You put your life on hold every time you look at your phone. Whether or not your phone is to blame for taking you out of the moment, a commitment to monitoring the quality of your attention to the present will raise your happiness levels a noticeable amount.
Pt's were asked to consider two self-interventions when thoughts became dark. One, drop everything and write a quick handwritten list of five coping statements/affirmations that either remind you of the value of this moment or your ability to overcome adversity. Two, run through your mind a list of three things you're grateful for and why. Client were educated that these exercises are simple but wildly effective if practiced daily or even a few times a week.
Client discussed several reason they are grateful including their recovery, family, job, health, etc
Counselor asked group member to ask themselves, "How often do I judge people for being wrong, bad or stupid, and what is true price I pay for these judgments?"
Counselor explained the least happy people are the ones who judge the most. Counselor states he is referring to people who are in the business of making others wrong. Rather than behave in a way that demonstrates their good qualities, these people aim to lower the value of people around them through insults and dark sarcasm. All humans judge. We'll never stop judging. Group members were educated that it's really about understanding the price you pay for judging. If you must judge, do it in your head and point out to yourself that you just judged. For example, say, "Yep, here I go judging again." Judgment generates anger and emotional distance. Most importantly, judgment kills cells in the body, so if you want to live long, commit to separating yourself from your judgments.

Client were asked two questions.
Which family member do I resent the most for their attitude/behavior?
Which family member do I resemble the most in terms of attitude/behavior?
Counselor informed the group members if the answer to both was the same person, then they needed to step away from their screens as soon as possible and increase their self-reflection because they were likely to be judging someone for the same behaviors that they're guilty of.
Client's pointed to different members of their family as those they resent the most.

Counselor discussed a quote: All of the world is a mirror. What you can't stand in others is what you struggle within yourself.

Clients were asked what they gain from their resentment. Was it power? Safety? Distance? Control? The illusion of winning? Client offered differing answers including a sense of control, not feeling bad about themselves, power, control, safety, keeping that person away, etc.

Counselor discussed moving toward learning to forgive might seem like too tall a task when it comes to the one family member you resent the most. Similar to learning to be more in the moment, building a well-developed muscle of forgiveness is one of the main keys to a happy life. It was explained this will also deepen your love toward the people

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Date: 5/19/2021
Time: 13:23:32

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you don't resent... yet, because people who don't deal with their primary resentments tend to have a hard time maintaining long-term, successful relationships.

Assessment/ Plan: Group members were asked to strive to check in with themselves and allocate time and energy toward answering what's taking them out of the moment, what they can do to overcome dark thoughts when there are no distractions and how they can distance themselves from their judgments and process their resentments. Counselor thanked the group for their feedback and asked that they carry this info into the coming weeks.

Entered By: Shawn Landreth — 4/7/2021 9:41:40 AM (Date)

599. This group therapy session did not occur and, instead, was an exact duplicate of a note previously used for other patients by other counselors and therapists.

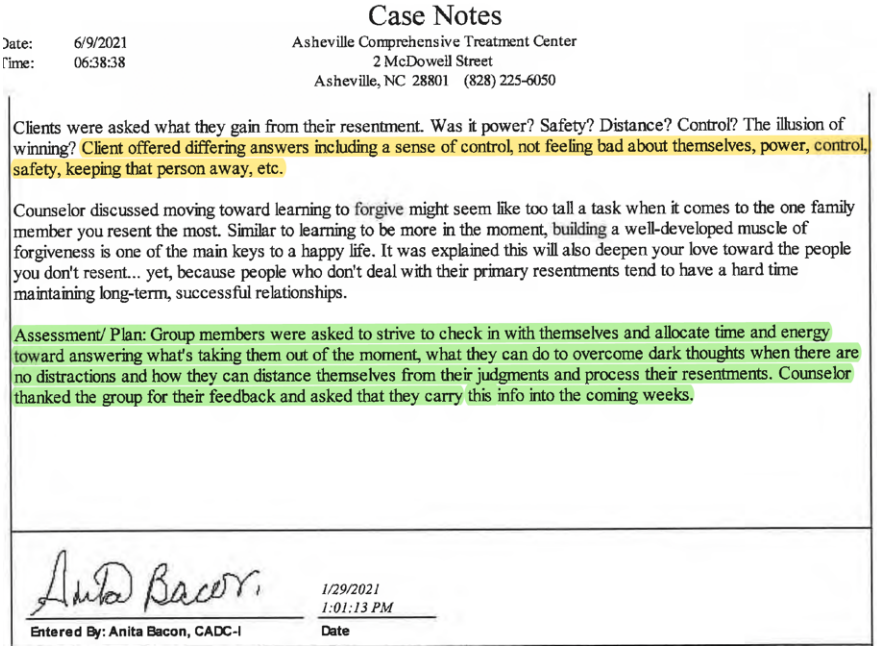
600. Counselor Anita Bacon signed a note for Patient 1 on January 29, 2021 that is identical to Patient 6's April 7, 2021 note.

1/25/2021	1 Units	Group Note	Group Note	09:45 AM-10:00 AM (15 min.)

Group Note - Data: Group Leader facilitated a continuous lobby group while observing the CDC's guidelines on social distancing and use of facemasks. Counselor engaged clients in a group session on a topic of "What prevents me from being in the moment?" Counselor explained to members the question is so important to answer because any effort you make to find greater happiness or grow as a person will be relatively useless if too many things take you away from appreciating the present moment. Counselor explained that one can't remain present all of the time, but should try to when it counts.
Counselor explained if the answer is "my phone or social media", then it was recommend to develop a habit of turning off your phone in 30-minute increments or making airplane mode their best friend. Counselor discussed creating tiny phone-less moments. Counselor discussed if work or relationship obligations prevented them from distancing themselves from their phones, they were told try keeping your phone on ringer and leaving it in another room. Some of the clients in the group discussed the fact they were doing these things and others discussed trying to in the coming week. One client on the line stated he goes for walks and leaves his phone at home just "to get away from the noise".
It was discussed that evolving the ability to distance yourself from your phone is working on just about the same mental muscle as distancing yourself from bad thoughts. If you can't separate from your phone, think about the following fact: You put your life on hold every time you look at your phone. Whether or not your phone is to blame for taking you out of the moment, a commitment to monitoring the quality of your attention to the present will raise your happiness levels a noticeable amount.
Pt's were asked to consider two self-interventions when thoughts became dark. One, drop everything and write a quick handwritten list of five coping statements/affirmations that either remind you of the value of this moment or your ability to overcome adversity. Two, run through your mind a list of three things you're grateful for and why. Client were educated that these exercises are simple but wildly effective if practiced daily or even a few times a week. Client discussed several reason they are grateful including their recovery, family, job, health, etc
Counselor asked group member to ask themselves, "How often do I judge people for being wrong, bad or stupid, and what is true price I pay for these judgments?"
Counselor explained the least happy people are the ones who judge the most. Counselor states he is referring to people who are in the business of making others wrong. Rather than behave in a way that demonstrates their good qualities, these people aim to lower the value of people around them through insults and dark sarcasm. All humans judge. We'll never stop judging. Group members were educated that it's really about understanding the price you pay for judging. If you must judge, do it in your head and point out to yourself that you just judged. For example, say, "Yep, here I go judging again." Judgment generates anger and emotional distance. Most importantly, judgment kills cells in the body, so if you want to live long, commit to separating yourself from your judgments.

Client were asked two questions.
Which family member do I resent the most for their attitude/behavior?
Which family member do I resemble the most in terms of attitude/behavior?
Counselor informed the group members if the answer to both was the same person, then they needed to step away from their screens as soon as possible and increase their self-reflection because they were likely to be judging someone for the same behaviors that they're guilty of.
Client's pointed to different members of their family as those they resent the most.

Counselor discussed a quote: All of the world is a mirror. What you can't stand in others is what you struggle within yourself.



Case Notes

Date: 6/9/2021
Time: 06:38:38

Asheville Comprehensive Treatment Center
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Asheville, NC 28801 (828) 225-6050

Clients were asked what they gain from their resentment. Was it power? Safety? Distance? Control? The illusion of winning? Client offered differing answers including a sense of control, not feeling bad about themselves, power, control, safety, keeping that person away, etc.

Counselor discussed moving toward learning to forgive might seem like too tall a task when it comes to the one family member you resent the most. Similar to learning to be more in the moment, building a well-developed muscle of forgiveness is one of the main keys to a happy life. It was explained this will also deepen your love toward the people you don't resent... yet, because people who don't deal with their primary resentments tend to have a hard time maintaining long-term, successful relationships.

Assessment/ Plan: Group members were asked to strive to check in with themselves and allocate time and energy toward answering what's taking them out of the moment, what they can do to overcome dark thoughts when there are no distractions and how they can distance themselves from their judgments and process their resentments. Counselor thanked the group for their feedback and asked that they carry this info into the coming weeks.

Anita Bacon

Entered By: Anita Bacon, CADC-I

1/29/2021
1:01:13 PM
Date

601. Counselor Ernest Davis signed the same note for Patient 7 on January 26, 2021.

602. Counselor Anita Bacon signed the same note for Patient 8 on April 6, 2021.

603. Counselor Shawn Landreth signed the same note for Patient 9 on April 6, 2021.

604. Counselor Anita Bacon signed the same note for Patient 10 on April 8, 2021.

605. Counselor Anita Bacon signed the same note for Patient 11 on April 12, 2021.

606. Counselor Shawn Landreth signed the same note for Patient 3 on April 6, 2021.

607. Counselor Anita Bacon signed the same note for Patient 3 on April 13, 2021.

608. Counselor Shawn Landreth signed the same note for Patient 12 on April 7, 2021.

609. Counselor Anita Bacon signed the same note for Patient 12 on April 13, 2021.

610. These duplicate notes also all state that they are "continuous lobby group(s)."

611. However, the notes also state that "[o]ne client on the line stated he goes for walks and leaves his phone at home just 'to get away from the noise'."

612. This statement in the duplicate notes implies that the fabricated group therapy session occurred by telephone.

613. The duplicate notes are not designated as telehealth notes, and a telehealth group therapy session would not be held in the lobby of the Asheville facility.

614. Upon information and belief, the Asheville facility did not have the technical capability to conduct telehealth group therapy sessions.

615. Moreover, the notes for Patient 3 and Patient 12 state that they participated in *identical* group therapy sessions during two consecutive weeks.

616. The group therapy sessions in these duplicate notes never happened, and Defendants falsified the records.

617. Upon information and belief, Defendants implemented a pattern and practice of creating falsified group therapy notes and duplicating them with different patients and counselors.

618. Patient 6's records also contain duplicate falsified group therapy notes for April 15, 2021; April 21, 2021; and April 28, 2021.

619. Patient 6 did not participate in any of these group therapy sessions.

620. Defendants did not hold any group therapy sessions at the Asheville facility on these dates.

621. Defendants continued to document in Patient 6's treatment plans that he would participate in all counseling requirements.

622. A counselor met with Patient 6 on July 13, 2021 to update his treatment plan.

623. The updated treatment plan notes that Patient 6's two previous drug screens were positive.

624. Patient 6 told the counselor that he was "struggling to stay abstinent" and "has a hard time processing his past traumas . . . ."

625. Patient 6 expressed interest in group therapy "and reported success with them in the past."

626. The counselor's assessment stated that Patient 6 was "dealing with unresolved trauma leading to using triggers" and stated that Patient 6 could benefit from "the support and community of group thearpy (sic)."

627. Patient 6's updated treatment plan stated: "The client will continue to attend counseling sessions through telehealth or in person sessions and abstain from illicit drug use. The counselor will help the patient begin the process of working through the unresolved trauma as well as start to develop the coping skills to help combat these triggers and intrusive thoughts in a healthier way moving froward (sic). [Patient 6] could benefit from attending group thearpy (sic) as well."

628. However, Patient 6's treatment plan did not state the frequency with which he should receive group therapy.

629. Upon information and belief, Patient 6 did not receive any group therapy at the Asheville facility at any point prior to Relator leaving her position as Assistant Medical Director in December 2021.

630. Upon information and belief, Defendants submitted bills to Medicare for weekly bundles of OTP services—including group therapy—during every week in April 2021 and during the week of Patient 6's May 19, 2021 visit with Relator.

631. Upon information and belief, Defendants submitted bills to Medicaid for OTP services—including group therapy—during every week in April 2021 and during the week of Patient 6's May 19, 2021 visit with Relator.

632. No group therapy was performed during any of these weeks.

633. Upon information and belief, Defendants expressly and/or impliedly certified to the United States and the State of North Carolina that they were in compliance with Patient 6's treatment plan; Federal and State law; OTP regulations, statutes, and standards; SAMHSA certification requirements; CARF accreditation requirements; their Provider Agreements; and the CIA.

634. These certifications were material to the United States and the State of North Carolina's payment decision.

635. Upon information and belief, the United States and the State of North Carolina—unaware of the falsity of Defendants' certifications—paid the claims for Patient 6's May 19, 2021 treatment and each week of April 2021.

636. Upon information and belief, Defendants submitted—and continue to submit—claims to Medicare and Medicaid for Patient 6's OTP services despite not complying with his treatment plan, not performing group therapy, and falsifying records.

637. Upon information and belief, Defendants were paid—and continue to be paid—claims by Medicare and Medicaid for Patient 6's OTP services despite not complying with his treatment plan, not performing group therapy, and falsifying records.

VIII. DEFENDANTS' SUBMISSION OF FALSE AND FRAUDULENT CLAIMS TO GOVERNMENT HEALTHCARE PROGRAMS

638. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

A. Defendants Submitted False and Fraudulent Claims to Government Healthcare Programs

639. Defendants provide OTP and OBOT services to Government Healthcare Program beneficiaries.

640. Defendants submit bills to Government Healthcare Programs for these OTP and OBOT patients.

641. As a component of this billing, Defendants bill Government Healthcare Programs for individual and group therapy for OTP and OBOT patients.

642. Government Healthcare Programs reimburse Defendants for individual and group therapy for OTP and OBOT patients.

643. Government Healthcare Programs reimburse Defendants either directly for individual and group therapy or as part of a bundled payment.

644. As detailed above, Defendants do not provide group therapy to any patients at the Asheville facility or the North Wilkesboro facility.

645. Upon information and belief, the falsification of these group therapy notes is knowingly performed at the direction of Defendants at the corporate level.

646. Defendants also provided inadequate individual therapy to patients at the Asheville facility.

647. Defendants engaged in—and continue to engage in—a pattern and practice of falsifying group therapy records for Government Healthcare Program beneficiaries at the Asheville and North Wilkesboro facilities.

648. This pattern and practice necessarily led to the submission of false and fraudulent claims for group therapy to Government Healthcare Programs for patients at the Asheville and North Wilkesboro facilities.

649. Government Healthcare Programs paid—and, upon information and belief, continue to pay—those claims without knowledge of the falsity of the claims.

650. Defendants knowingly made false statements, implied certifications, and express certifications that were material to the Government Healthcare Programs' decisions to pay claims for group therapy at the Asheville and North Wilkesboro facilities and individual therapy at the Asheville facility.

651. Upon information and belief, Defendants do not provide group therapy to OTP and OBOT Government Healthcare Program beneficiaries at many other facilities.

652. Upon information and belief, Defendants engaged in—and continue to engage in—a pattern and practice of falsifying group therapy records for Government Healthcare Program beneficiaries.

653. Upon information and belief, this pattern and practice necessarily led to the submission of false and fraudulent claims for group therapy to Government Healthcare Programs.

654. Upon information and belief, Government Healthcare Programs paid—and continue to pay—those claims without knowledge of the falsity of the claims.

655. Upon information and belief, Defendants knowingly made false statements, implied certifications, and express certifications that were material to the Government Healthcare Programs' decisions to pay claims for group therapy.

B. Defendants' Express and/or Implied False Certifications to Government Healthcare Programs

656. Each time Defendants submitted a claim for individual or group therapy to a Government Healthcare Program, either as an individual bill or as part of a bundled bill, they made express and/or implied false certifications of compliance with:

a. Federal law, regulations, and treatment standards;

b. North Carolina law;

c. SAMHSA certification requirements;

d. SAMHSA accreditation requirements;

e. Provider agreements; and

f. The CIA.

657. Upon information and belief, Defendants engaged in—and continue to engage in—a pattern and practice of expressly and/or impliedly falsely certifying compliance with these laws, regulations, standards, requirements, and agreements.

658. Government Healthcare Programs paid—and continue to pay—claims for group therapy that did not occur without knowledge of the falsity of Defendants' express and/or implied certifications.

659. Government Healthcare Programs paid—and continue to pay—claims for inadequate individual therapy without knowledge of the falsity of Defendants' express and/or implied certifications.

660. Defendants' express and/or implied false certifications were material to Government Healthcare Programs' payment decisions.

661. Upon information and belief, if Government Healthcare Programs were aware of the falsity of Defendants' express and/or implied certifications, they would not have reimbursed Defendants for individual and/or group therapy—including through CMS's bundled payment process.

1. Defendants' Express and/or Implied False Certifications of Compliance with Federal Law, Regulations, and Treatment Standards

662. Defendants expressly and/or impliedly certified to Government Healthcare Programs that the Asheville and North Wilkesboro facilities were complying with federal OTP laws, regulations, and standards.

663. These certifications were false.

664. Defendants were not—and, upon information and belief, are not—providing adequate counseling services to Government Healthcare Program beneficiaries at the Asheville and North Wilkesboro facilities.. *See* 42 C.F.R. §§ 8.12(f)(1), (f)(5)(i); 42 C.F.R. § 410.67(b)(4).

665. Defendants were not—and, upon information and belief, are not—providing any group therapy to Government Healthcare Program beneficiaries at the Asheville and North Wilkesboro facilities.. *See id.*

666. Defendants were—and, upon information and belief, are—providing inadequate individual therapy to Government Healthcare Program beneficiaries at the Asheville facility. *See id.*

667. Defendants were—and, upon information and belief, still are—providing minimal individual therapy by audio-only telephone calls without first determining that face-to-face or audio/video communication was not available to patients at the Asheville facility. *See id.*

668. Defendants did not "establish and maintain a recordkeeping system that is adequate to document and monitor patient care" at the Asheville and North Wilkesboro facilities. 42 C.F.R. § 8.12(g)(1).

669. Defendants knowingly and systematically falsified group therapy records for patients—including Government Healthcare Program beneficiaries—at the Asheville and North Wilkesboro facilities.

670. Defendants were not—and, upon information and belief, are not—complying with the requirements of patients' treatment plans or adequately reviewing and updating patients' treatment plans to reflect patients' evolving counseling and therapy needs at the Asheville and North Wilkesboro facilities.. *See* 42 C.F.R. § 8.12(f)(4).

671. These patterns and practices violate federal OTP laws, regulations, and standards.

672. Upon information and belief, Defendants' falsification of group therapy records is a corporate policy that occurs at Defendants' facilities across the United States.

673. Upon information and belief, Defendants engaged in a pattern and practice of falsely expressly and/or impliedly certifying compliance with federal OTP laws, regulations, and standards at facilities across the United States.

674. These false express and/or implied certifications were material to the Government Healthcare Programs' decisions to pay Defendants' claims for individual and/or group therapy.

2. Defendants' Express and/or Implied False Certifications of Compliance with North Carolina Law

675. Defendants' pattern and practice of failing to provide group therapy violates the State of North Carolina's OBOT and OTP laws, regulations, and/or standards.

676. Defendants' pattern and practice of falsifying group therapy records violates the State of North Carolina's OBOT and OTP laws, regulations, and/or standards.

677. Defendants' failure to provide adequate counseling and/or therapy to patients violates the State of North Carolina's OBOT and OTP laws, regulations, and/or standards.

678. Defendants' failure to properly document the frequency and type of therapy and/or counseling in patient treatment plans violates the State of North Carolina's OBOT and OTP laws, regulations, and/or standards.

679. Defendants' failure to comply with the counseling and/or therapy requirements in patient treatment plans violates the State of North Carolina's OBOT and OTP laws, regulations, and/or standards.

680. Defendants engaged in a pattern and practice of falsely expressly and/or impliedly certifying compliance with the State of North Carolina's OBOT and OTP laws, regulations, and/or standards.

681. These false express and/or implied certifications were material to Government Healthcare Programs' decisions to pay Defendants' claims for individual and/or group therapy.

3. Defendants' Express and/or Implied False Certifications of Compliance with SAMHSA Certification Requirements

682. In order to obtain SAMHSA certification, OTPs must complete the accreditation process and satisfy the federal OTP laws, regulations, and standards.

683. Defendants applied to SAMHSA to obtain certification for the Asheville and North Wilkesboro facilities.

684. Upon information and belief, Defendants signed statements that the Asheville and North Wilkesboro facilities would comply with the conditions of certification set forth in 42 C.F.R. § 8.11(f). *See* 42 C.F.R. § 8.11(b)(6).

685. SAMHSA's conditions of certification require OTPs to, *inter alia*, comply with state laws and regulations and "operate in accordance with Federal opioid treatment standards and approved accreditation elements." 42 C.F.R. § 8.11(f).

686. As detailed above, Defendants have failed to comply with federal OTP laws, regulations, and standards by failing to provide adequate counseling services at the Asheville and North Wilkesboro facilities.

687. As detailed above, Defendants have failed to comply with federal OTP laws, regulations, and standards by failing to provide group therapy at the Asheville and North Wilkesboro facilities.

688. As detailed above, Defendants have failed to comply with federal OTP laws, regulations, and standards by falsifying group therapy records at the Asheville and North Wilkesboro facilities.

689. As detailed above, Defendants have failed to comply with federal OTP laws, regulations, and standards by failing to provide adequate individual therapy at the Asheville facility.

690. As detailed above, Defendants have failed to comply with federal OTP laws, regulations, and standards by failing to "establish and maintain a recordkeeping system that is adequate to document and monitor patient care" at the Asheville and North Wilkesboro facilities. 42 C.F.R. § 8.12(g)(1).

691. As detailed above, Defendants have failed to comply with the requirements of patients' treatment plans and failed to adequately review and update patients' treatment plans to reflect patients' evolving counseling and therapy needs at the Asheville and North Wilkesboro facilities.. *See* 42 C.F.R. § 8.12(f)(4).

692. This conduct violates Defendants' SAMHSA certifications at the Asheville and North Wilkesboro facilities.

693. Upon information and belief, all of the OTPs owned and/or operated by Defendants across the United States are certified by SAMHSA.

694. Upon information and belief, Defendants signed statements that these facilities would comply with the conditions of certification set forth in 42 C.F.R. § 8.11(f). *See* 42 C.F.R. § 8.11(b)(6).

695. Upon information and belief, Defendants' failure to provide group therapy and falsification of group therapy records is a corporate policy that has occurred—and continues to occur—at facilities across the United States.

696. Upon information and belief, Defendants fail to provide adequate counseling for patients at their facilities across the United States.

697. Upon information and belief, the above conduct violates Defendants' SAMHSA certifications.

698. Upon information and belief, Defendants have engaged in a pattern and practice of falsely expressly and/or impliedly certifying compliance with their SAMHSA certifications.

699. These false express and/or implied certifications were material to Government Healthcare Programs' decisions to pay Defendants' claims for individual and/or group therapy.

4. Defendants' Express and/or Implied False Certifications of Compliance with SAMHSA Accreditation Requirements

700. In order to become certified by SAMHSA, OTPs must obtain a "current, valid accreditation by an accreditation body or other entity designated by SAMHSA . . . ." 42 C.F.R. § 8.11(a)(2).

701. The Asheville and North Wilkesboro facilities were accredited by CARF.

702. Upon information and belief, Defendants' failure to provide adequate counseling for patients at the Asheville and North Wilkesboro facilities violates CARF's accreditation standards.

703. Upon information and belief, Defendants' failure to provide group therapy and falsification of group therapy records at the Asheville and North Wilkesboro facilities violate CARF's accreditation standards.

704. Upon information and belief, Defendants' violations of federal OTP laws, regulations, and standards violate CARF's accreditation standards.

705. Upon information and belief, Defendants' violations of the State of North Carolina's OBOT and OTP laws, regulations, and/or standards violate CARF's accreditation standards.

706. Upon information and belief, Defendants' other OTPs have been accredited by CARF or other SAMHSA approved accreditation bodies.

707. Upon information and belief, Defendants' failure to provide adequate counseling for patients violates the accreditation standards of the SAMHSA approved accreditation organizations that accredited Defendants' facilities.

708. Upon information and belief, Defendants' failure to provide group therapy and falsification of group therapy records violates the accreditation standards of the SAMHSA approved accreditation organizations that accredited Defendants' facilities.

709. Upon information and belief, Defendants' failure to comply with federal OTP laws, regulations, and standards violates the accreditation standards of the SAMHSA approved accreditation organizations that accredited Defendants' facilities.

710. Upon information and belief, Defendants have engaged in a pattern and practice of falsely expressly and/or impliedly certifying compliance with their SAMHSA approved accreditations.

711. These false express and/or implied certifications were material to Government Healthcare Programs' decisions to pay Defendants' claims for individual and/or group therapy.

5. Defendants' Express False Certifications of Compliance with Provider Agreements

712. Upon information and belief, Defendants have provider agreements with Government Healthcare Programs, including Medicare, TRICARE, the VA, the State of North Carolina Medicaid Program, North Carolina LME/MCOs, other state Medicaid Programs, and state organizations authorized to distribute Cures Act funding.

713. Upon information and belief, Defendants' failure to provide adequate counseling to patients violates their provider agreements.

714. Upon information and belief, Defendants' failure to provide group therapy violates their provider agreements.

715. Upon information and belief, Defendants' falsification of group therapy records violates their provider agreements.

716. Upon information and belief, Defendants' failure to comply with federal OTP laws, regulations, and standards violates their provider agreements.

717. Upon information and belief, Defendants' failure to comply with state OBOT and OTP laws, regulations, and standards violates their provider agreements.

718. Upon information and belief, Defendants have engaged in a pattern and practice of falsely expressly and/or impliedly certifying compliance with their provider agreements.

719. These false express and/or implied certifications were material to Government Healthcare Programs' decisions to pay Defendants' claims for individual and/or group therapy.

6. Defendants' Express and/or Implied False Certifications of Compliance with the CIA

720. As detailed above, Defendants are subject to the requirements of the CIA.

721. Defendants did not provide Relator with any annual training related to their obligations under the CIA until May 2021.

722. Nor, upon information and belief, did Defendants provide Relator with written information about the Compliance Program or Disclosure Program until May 2021.

723. Defendants have violated the requirements of the CIA in several ways.

724. On or about March 2021, Relator told the Clinic Director of the Asheville facility that Defendants were engaging in fraud by falsifying group therapy records.

725. On or about May 2021, Relator again told the Clinic Director of the Asheville facility that Defendants were engaging in fraud by falsifying group therapy records.

726. On or about July 2021, Relator again told the Clinic Director of the Asheville facility that Defendants were engaging in fraud by falsifying group therapy records.

727. Each of these constituted a "Reportable Event" under the terms of the CIA, and Defendants and their employees, agents, contractors, and subcontractors had a contractual obligation to report the fraudulent conduct to HHS-OIG.

728. Upon information and belief, Defendants knowingly failed to comply with that requirement in the CIA and are in material breach of the CIA.

729. Upon information and belief, Defendants did not log Relator's disclosure of fraud.

730. Upon information and belief, Defendants did not investigate Relator's disclosure of fraud.

731. Upon information and belief, Defendants did not take any remedial actions to stop the fraud Relator reported.

732. Upon information and belief, Defendants did not comply with policies and procedures designed to ensure adherence to the Compliance Program required by the CIA.

733. Upon information and belief, Defendants have signed the certifications and resolutions described above as required by the CIA.

734. These certifications, as required by the CIA, are express certifications that Defendants are complying with the terms of the CIA.

735. However, upon information and belief, Defendants have not actually performed the compliance activities or oversight required by the CIA.

736. Defendants have engaged in a pattern and practice of falsely expressly and/or impliedly certifying compliance with the CIA.

737. These false express and/or implied certifications were material to Government Healthcare Programs' decisions to pay Defendants' claims for individual and/or group therapy.

C. Government Healthcare Programs Paid Defendants Based on their Express and/or Implied False Certifications

738. Defendants' express and/or implied false certifications constitute a pattern or practice that has necessarily led to the submission of false claims to the United States and the State of North Carolina.

739. Compliance with the standards, contracts, laws, regulations, certifications, and accreditations detailed above are express and/or implied conditions of participation in the Government Healthcare Programs.

740. Compliance with these standards, contracts, laws, regulations, certifications, and accreditations are express and/or implied conditions of payment for MAT, OBOT, and/or OTP services by Government Healthcare Programs.

741. The United States and the State of North Carolina, unaware of the falsity of Defendants' certifications, have processed and paid claims submitted to Government Healthcare Programs based on Defendants' express and/or implied false certifications.

742. Defendants' express and/or implied false certifications as set forth above are material to Defendants' participation in Government Healthcare Programs.

743. Defendants' express and/or implied false certifications as set forth above are material to the United States' and the State of North Carolina's payment decisions for Government Healthcare Program claims for MAT, OBOT, and/or OTP services—including individual and/or group therapy.

744. As a result, every Government Healthcare Program claim submitted since at least September 2020 is a false claim.

COUNT I
Violations of the FCA: Presenting or Causing the Presentation of False Claims
31 U.S.C. § 3729(a)(1)(A)

745. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

746. In pertinent part, the FCA establishes liability for "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . ." 31 U.S.C. § 3729(a)(1)(A).

747. Defendants knowingly or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, presented or caused to be presented false claims "for payment or approval" to the United States in violation of 31 U.S.C. § 3729(a)(1)(A).

748. By virtue of the acts described above, the Defendants knowingly or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, presented or caused to be presented, false claims to officers, employees, or agents of the United States Government, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

749. The United States was unaware of the falsity of the records, statements, and claims made or caused to be made by Defendants. In reliance on the accuracy of the claims, information, records, and certifications submitted or caused to be submitted by Defendants, the United States paid claims that would not be paid if Defendants' illegal conduct was known.

750. As a result of Defendants' acts, the United States sustained damages and therefore is entitled to treble damages under the FCA to be determined at trial.

751. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

COUNT II
Violations of the FCA: Use of False Record or Statement Material to a False Claim
31 U.S.C. § 3729(a)(1)(B)

752. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

753. In pertinent part, the FCA establishes liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . ." *See* 31 U.S.C. § 3729(a)(1)(B).

754. By virtue of the acts described above, Defendants knowingly or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, made, used, or caused to be made or used, false records and statements.

755. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to get false claims paid or approved, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

756. The records and statements were false in that they purported to show compliance with Federal laws, regulations, and standards; State laws, regulations, and standards; SAMHSA certifications and accreditations; Defendants' provider agreements; and the CIA.

757. The records and statements were material to a false or fraudulent claim.

758. Defendants knowingly made, used, or caused to be made or used these false records or statements with the intent to get or cause these false claims to be paid by the United States.

759. The United States was unaware of the falsity of the records, statements, certifications, and claims made or caused to be made by the Defendants

760. The United States paid claims that would not be paid if Defendants' illegal conduct was known.

761. By virtue of this conduct, the United States sustained damages and therefore is entitled to treble damages under the False Claims Act to be determined at trial.

762. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

COUNT III
Violations of the FCA: Conversion
31 U.S.C. § 3729(a)(1)(D)

763. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

764. In pertinent part, the FCA establishes liability for "any person who . . . has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property . . . ." 31 U.S.C. § 3729(a)(1)(D).

765. Defendants violated this provision by knowingly keeping possession of Government Healthcare Program funds—including, but not limited to direct reimbursements and Cures Act grant money—that the Government intended Defendants to use for providing counseling and therapy services to patients with Opioid Use Disorder.

766. Additionally, the weekly bundled payments Defendants received from Government Healthcare Programs, including Medicare, included a non-drug component that included the Medicare physician fee schedule non-facility rates for, *inter alia*, 30 minutes of individual psychotherapy and a group psychotherapy session each week. *See* 42 C.F.R. § 410.67(d)(2)(ii)(A).

767. By knowingly failing to actually provide group therapy and adequate individual therapy, Defendants delivered less than all the United States intended them to deliver when they

failed to provide those therapy services and instead kept the reimbursements, bundled payments, and grant money for their own profit.

768. In sum, Defendants knowingly received reimbursement, bundled payments, and grant funding from the United States and state governments for government use—i.e., meeting the medical and behavioral needs of Government Healthcare Beneficiaries suffering from Opioid Use Disorder. Defendants converted that money for its own profit rather than the use intended by the United States and state governments.

769. By virtue of this conduct, the United States sustained damages and therefore is entitled to treble damages under the False Claims Act to be determined at trial.

770. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

COUNT IV
Violations of the FCA: Submission of Express and Implied False Certifications
31 U.S.C. § 3729(a)(1)(B)

771. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

772. In pertinent part, the FCA establishes liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . . ." 31 U.S.C. § 3729(a)(1)(B).

773. Compliance with applicable federal laws, regulations, and standards; North Carolina and other state laws; SAMHSA certifications; SAMHSA approved accreditations; provider agreements; and the CIA was an implied, and upon information and belief, also an express condition of Defendants' eligibility to participate in Government Healthcare Programs and provide reimbursable MAT, OBOT, and OTP services.

774. Compliance with applicable federal laws, regulations, and standards; North Carolina and other state laws; SAMHSA certifications; SAMHSA approved accreditations; provider agreements; and the CIA was an implied, and upon information and belief, also an express condition of payment of claims submitted to the United States in connection with Defendants' fraudulent and illegal practices.

775. Defendants express and implied certifications of compliance with these laws, regulations, standards, certifications, accreditations, and contracts was knowingly false.

776. The United States, unaware of the falsity of the records, statements, certifications and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct, and the Defendants' illegal conduct was material to the Government's decision to pay claims.

777. By virtue of this conduct, the United States sustained damages and therefore is entitled to treble damages under the False Claims Act to be determined at trial.

778. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

COUNT V
Violations of the FCA: Fraudulent Inducement
31 U.S.C. § 3729(a)(1)(B)

779. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

780. By virtue of the acts described above, Defendants knowingly or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, made, used, or caused to be made or used, false records and statements.

781. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to get false claims paid or approved, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

782. The records and statements were false in that they purported to show that Defendants were providing group therapy, complying with Federal and State laws, satisfying the requirements of SAMHSA certifications and accreditations, and complying with the CIA.

783. Defendants knowingly made, used, or caused to be made or used these false records or statements with the intent to induce the United States and States to allow Defendants to participate in Government Healthcare Programs.

784. Defendants knowingly made, used, or caused to be made or used these false records or statements with the intent to induce the United States and States to certify, accredit, contract with, and authorize Defendants to provide MAT, OBOT, and/or OTP services to beneficiaries of Government Healthcare Programs.

785. The records and statements were material to a false or fraudulent claim.

786. The United States and States were unaware of the falsity of the records and statements.

787. The United States and States would not have allowed Defendants to participate in Government Healthcare Programs if they were aware of the falsity of Defendants' records and statements.

788. The United States and States would not have certified, accredited, contracted with, or authorized Defendants to provide MAT, OBOT, and/or OTP services to beneficiaries of Government Healthcare Programs if they were aware of the falsity of Defendants' records and statements.

789. The United States paid claims that would not have been paid if Defendants' illegal conduct was known.

790. By virtue of this conduct, the United States sustained damages and therefore is entitled to treble damages under the False Claims Act to be determined at trial.

791. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

COUNT VI
Violations of the FCA: Reverse False Claims
31 U.S.C. § 3729(a)(1)(G)

792. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

793. In pertinent part, the FCA also establishes liability for any person who "knowingly, makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government . . . ." 31 U.S.C. § 3729(a)(1)(G).

794. The FCA defines the term "obligation" to mean "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment . . . ." 31 U.S.C. § 3729(b)(3).

795. The CIA contains Stipulated Penalties for violations of its provisions.

796. Defendants violated the CIA by, *inter alia*, failing to implement or enforce compliance, training, and disclosure requirements and failing to disclose to HHS-OIG "Reportable Events."

797. Defendants violated the CIA by falsely certifying to the United States that they were in compliance with the requirements of the CIA.

798. By failing to comply with these provisions of the CIA, and concealing their violations of the CIA, Defendants knowingly made, used, or caused to be made or used, false records or statements material to an obligation to pay or transmit money or property to the Government.

799. Additionally, Defendants knowingly and improperly decreased and/or avoided their obligation to pay or transmit money, by way of Stipulated Penalties and overpayments, to the United States.

800. By virtue of this conduct, the United States sustained damages and therefore is entitled to treble damages under the False Claims Act to be determined at trial.

801. Additionally, the United States is entitled to civil penalties for each false claim made or caused to be made by Defendants arising from their illegal conduct as described above.

COUNT VII
Violations of the North Carolina False Claims Act
N.C. Gen. Stat. § 1-605, *et seq.*

802. Relator re-alleges and incorporates the allegations of the paragraphs above as if fully set forth herein.

803. As described above, Defendants knowingly and/or with deliberate ignorance or reckless disregard of the truth or falsity of the information presented or caused to be presented false or fraudulent claims for payment or approval to the State of North Carolina.

804. As described above, Defendants made, used or caused to be made or used false records or statements material to a false or fraudulent claim.

805. As described above, Defendants had possession, custody, or control of property or money used or to be used by the State and knowingly delivered or caused to be delivered less than all of that money or property.

806. As described above, compliance with applicable federal laws, regulations, and standards; North Carolina and other state laws; SAMHSA certifications; SAMHSA approved accreditations; provider agreements; and the CIA was an implied, and upon information and belief, also an express condition of Defendants' eligibility to participate in Government Healthcare Programs and provide reimbursable MAT, OBOT, and OTP services.

807. As described above, compliance with applicable federal laws, regulations, and standards; North Carolina and other state laws; SAMHSA certifications; SAMHSA approved accreditations; provider agreements; and the CIA was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' fraudulent and illegal practices.

808. As described above, Defendants' express and implied certifications of compliance with these laws, regulations, standards, certifications, accreditations, and contracts were knowingly false.

809. The State of North Carolina, unaware of the falsity of the records, statements, certifications and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct, and the Defendants' illegal conduct was material to the Government's decision to pay claims.

810. By reason of Defendants' acts, the State of North Carolina sustained damages and therefore is entitled to treble damages under the North Carolina False Claims Act to be determined at trial.

811. In addition, the State of North Carolina is entitled to recover civil monetary penalties, and other monetary relief as deemed appropriate.

PRAYER FOR RELIEF

WHEREFORE, Relator respectfully requests this Court to enter judgment against Defendants, as follows:

a. That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims and fraud alleged within this Complaint, as the FCA provides;

b. That the State of North Carolina be awarded damages in the amount of three times the damages sustained by the State of North Carolina because of the false claims and fraud alleged within this Complaint, as the North Carolina False Claims Act provides;

c. That civil penalties in the maximum amount allowable by law be imposed for each and every false claim that Defendants presented to the United States and/or its agencies;

d. That civil penalties in the maximum amount allowable by law be imposed for each and every false claim that Defendants presented to the State of North Carolina and/or its agencies;

e. That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, expert fees, and expenses which Relator necessarily incurred in bringing and pressing this case;

f. That the Court grant permanent injunctive relief to prevent any recurrence of the FCA and the North Carolina False Claims Act for which redress is sought in this Complaint;

g. That Relator be awarded the maximum amount (i.e., relator's share) allowed to her pursuant to the FCA and the North Carolina False Claims Act; and

h. That this Court award such other and further relief as it deems proper.

DEMAND FOR JURY TRIAL

Relator, on behalf of herself, the United States, and the State of North Carolina, demands a jury trial on all claims triable alleged herein.

Respectfully submitted,

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